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(12) **United States Patent**  
**Kuang et al.**

(10) **Patent No.:** **US 11,464,630 B2**  
(45) **Date of Patent:** **Oct. 11, 2022**

(54) **STENT DEVICE WITH SKIRT FOLDS AND PROCESSING METHOD THEREOF, SKIRT FOLDING METHOD, AND HEART VALVE**

(58) **Field of Classification Search**  
CPC .... A61F 2/2409; A61F 2/2412; A61F 2/2418; A61F 2250/0069  
See application file for complete search history.

(71) Applicant: **VENUS MEDTECH (HANGZHOU), INC.**, Zhejiang (CN)

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(72) Inventors: **Dajun Kuang**, Hangzhou (CN); **Jesse Jun Qi**, Irvine, CA (US); **Min Frank Zeng**, Irvine, CA (US); **Jincheng Yu**, Hangzhou (CN); **Lo Pham**, Irvine, CA (US); **Lai Nguyen**, Irvine, CA (US)

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(73) Assignee: **Venus Medtech (Hangzhou) Inc.**, Hangzhou (CN)

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(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(21) Appl. No.: **16/807,412**

International Search Report dated Nov. 29, 2018 for corresponding PCT Application No. PCT/CN2018/103917.

(22) Filed: **Mar. 3, 2020**

Office Action dated May 3, 2021 for corresponding European Application No. 18852140.5.

(65) **Prior Publication Data**

US 2020/0289260 A1 Sep. 17, 2020

*Primary Examiner* — Suba Ganesan

(74) *Attorney, Agent, or Firm* — Raymond Sun

**Related U.S. Application Data**

(63) Continuation of application No. PCT/CN2018/103917, filed on Sep. 4, 2018.

(57) **ABSTRACT**

A stent device with skirt folds and a processing method thereof, a skirt folding method, and a heart valve. The stent device comprises a stent (1, 10) and a flexible skirt (2, 107), the skirt (2, 107) having an expanded state, in which the skirt is axially extended and surrounds the stent (1, 105) before release thereof, and a folded state, in which the skirt is driven by the deformation caused when the stent (1, 105) is released, collapses and folds axially along the released stent (1, 105) so as to form an annular peripheral leakage-blocking portion. The peripheral leakage prevention technology enables an interventional stent to fit to the inner wall of a vessel more snugly, such that the stent does not easily move and is more stable, thereby being suitable for more people, reducing additional risks of surgery and preventing complications such as peripheral leakage and thrombus. The

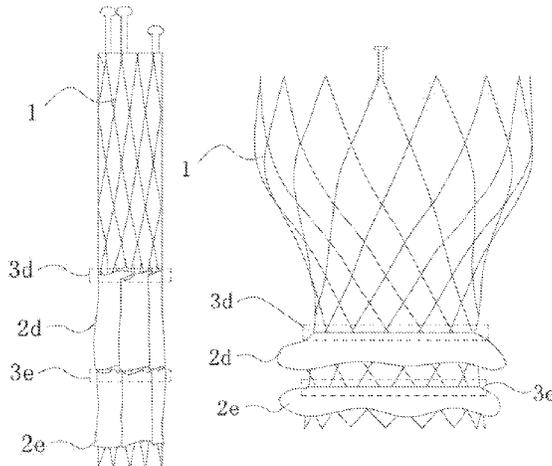
(Continued)

(30) **Foreign Application Priority Data**

Sep. 4, 2017 (CN) ..... 201710786392.2  
Oct. 28, 2017 (CN) ..... 2017111031064.8

(51) **Int. Cl.**  
**A61F 2/24** (2006.01)

(52) **U.S. Cl.**  
CPC ..... **A61F 2/2418** (2013.01); **A61F 2/2409** (2013.01); **A61F 2/2415** (2013.01);  
(Continued)



present disclosure can provide better blood dynamics, increase the crawling capability of endothelial cells of a host, reduce the probability of occurrence of endocarditis, and restore a normal blood supply functionality of vessels.

10 Claims, 29 Drawing Sheets

(52) U.S. Cl.

CPC ..... A61F 2/2433 (2013.01); A61F 2/2439 (2013.01); A61F 2210/0057 (2013.01); A61F 2220/0008 (2013.01); A61F 2220/0016 (2013.01); A61F 2220/0075 (2013.01); A61F 2250/0051 (2013.01); A61F 2250/0069 (2013.01)

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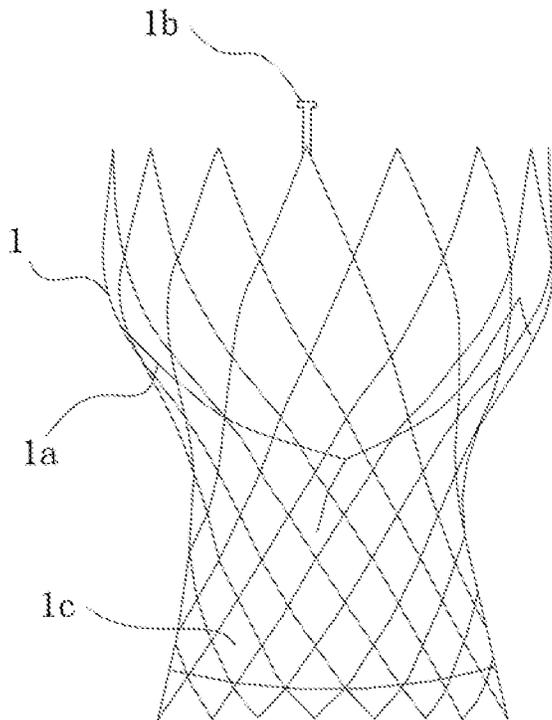


FIG. 1a (PRIOR ART)

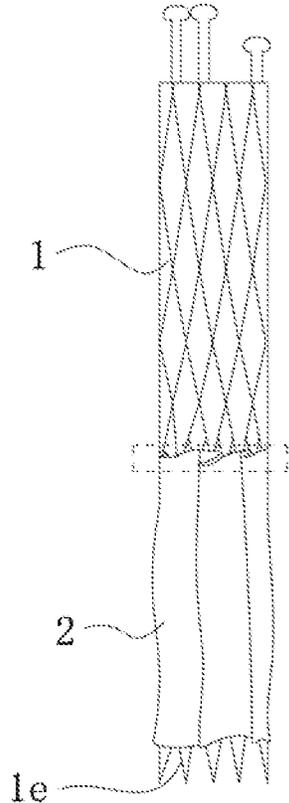


FIG. 1b

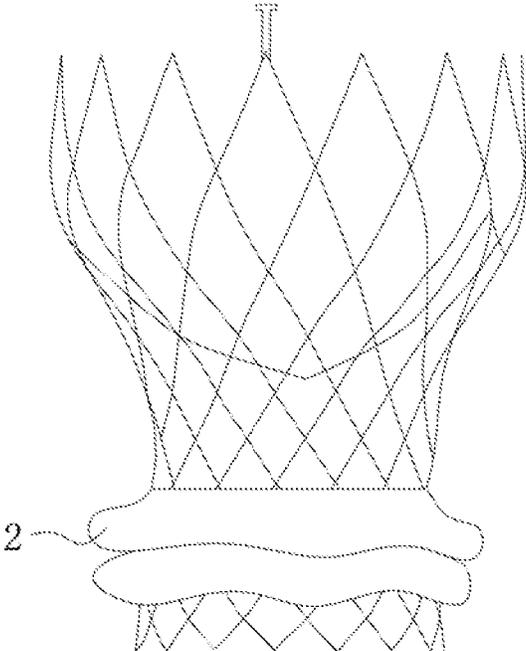


FIG. 1c

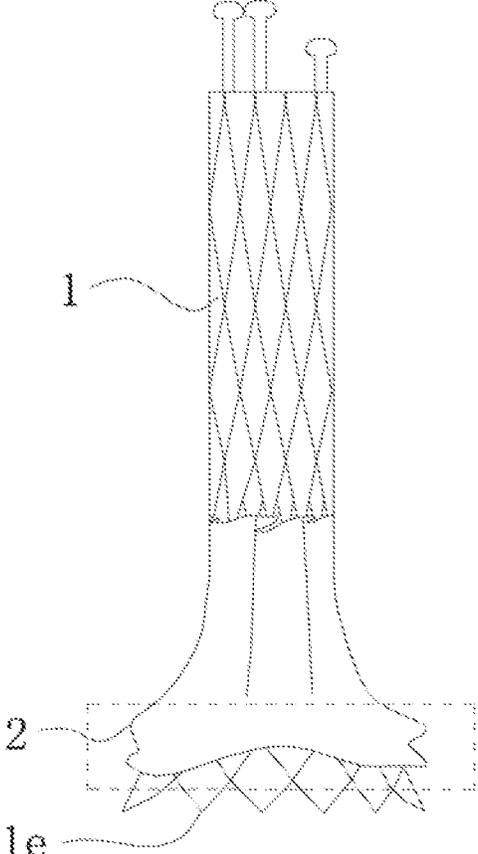


FIG. 1d

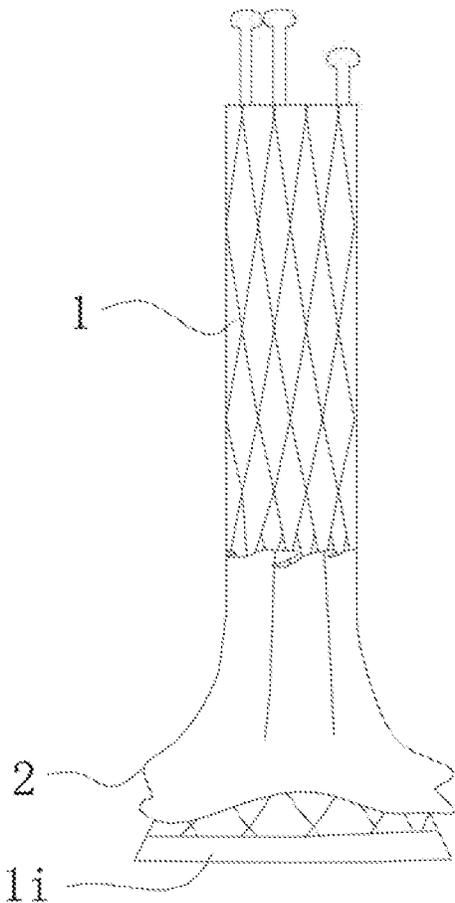


FIG. 1e

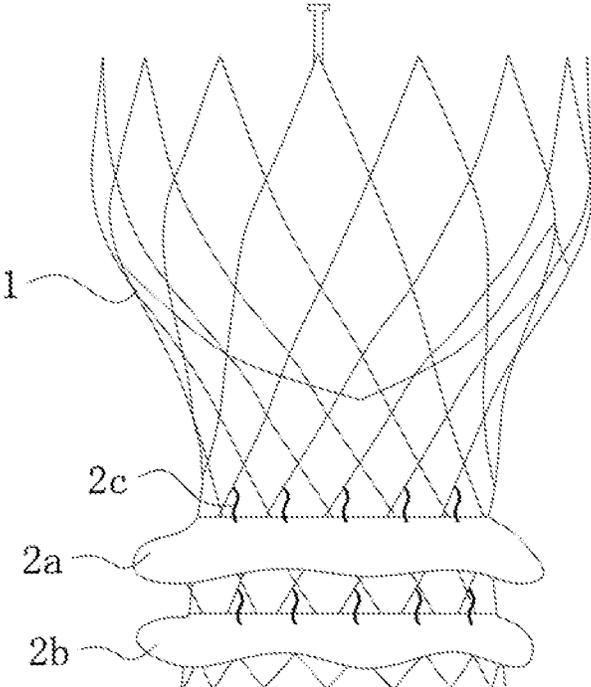


FIG. 2

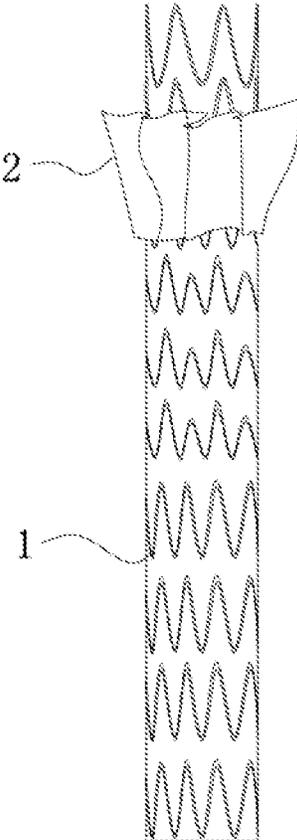


FIG. 3a

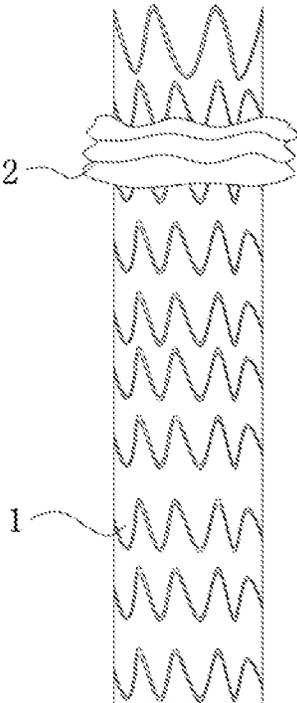


FIG. 3b

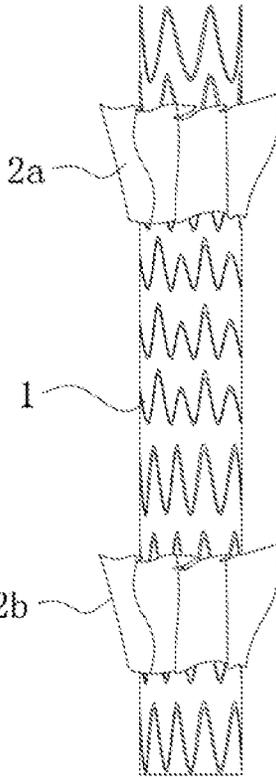


FIG. 4a

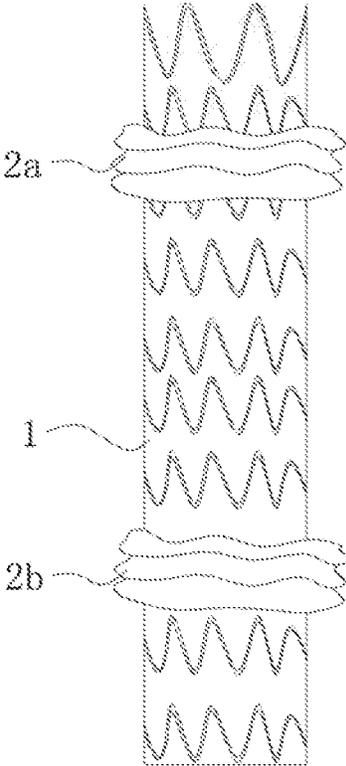


FIG. 4b

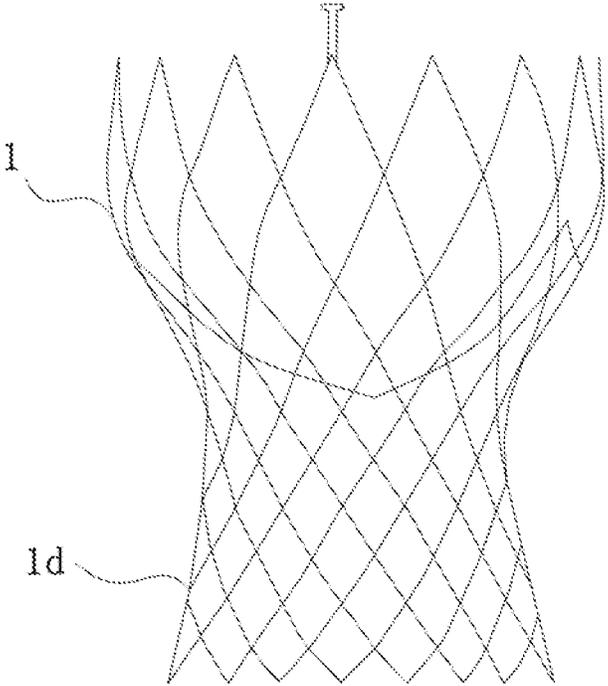


FIG. 5a

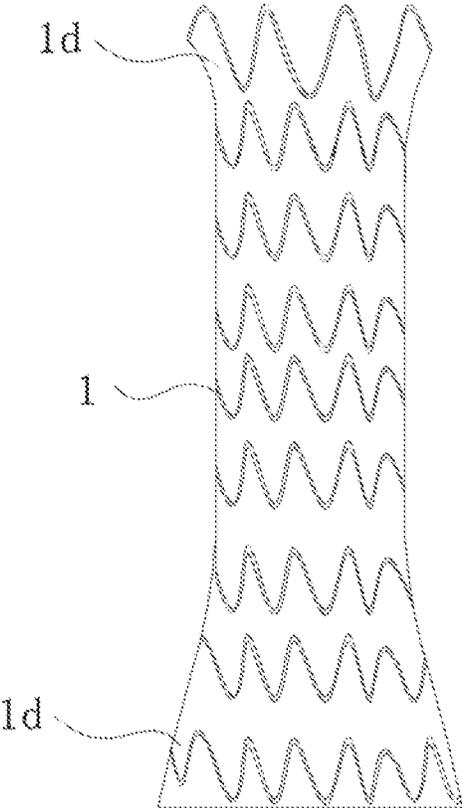


FIG. 5b

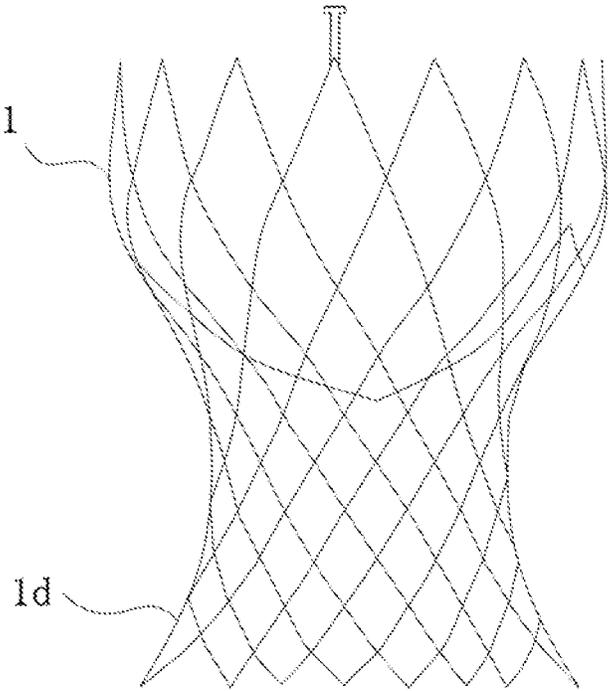


FIG. 6

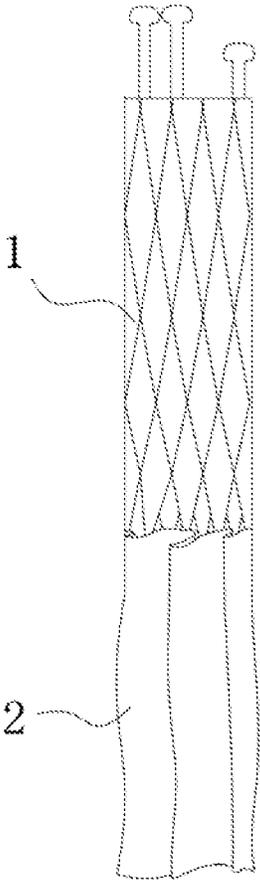


FIG. 7a

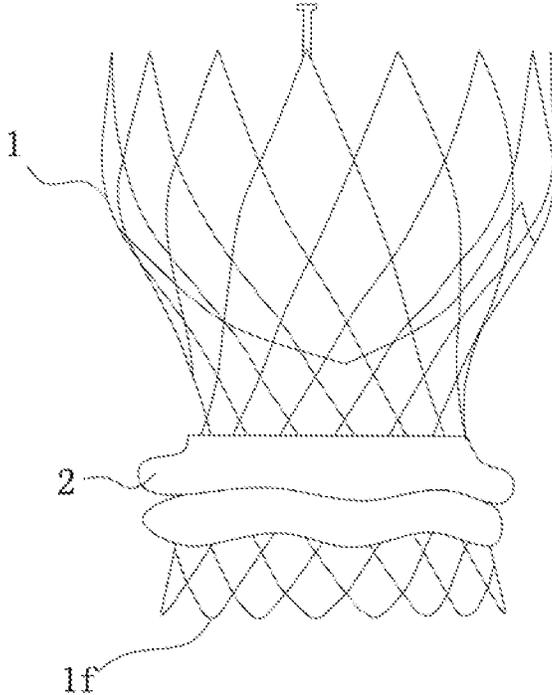


FIG. 7b

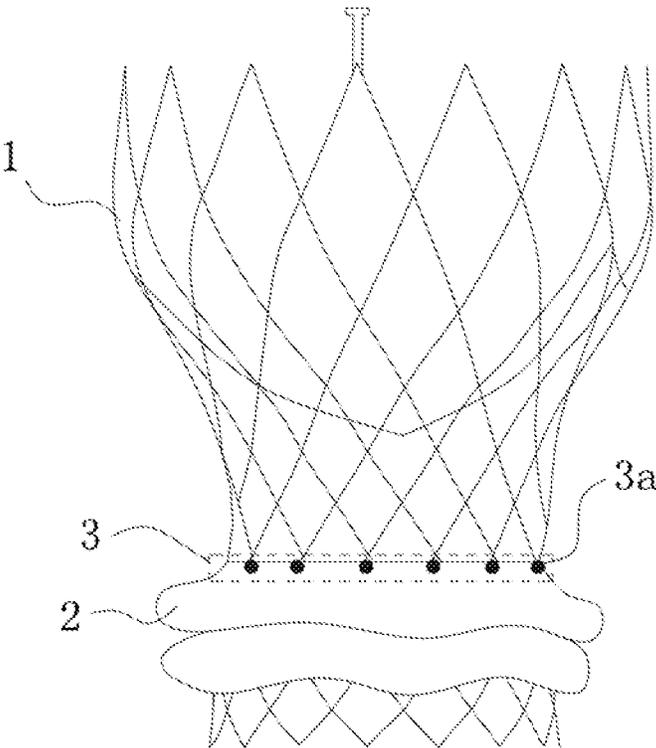


FIG. 8

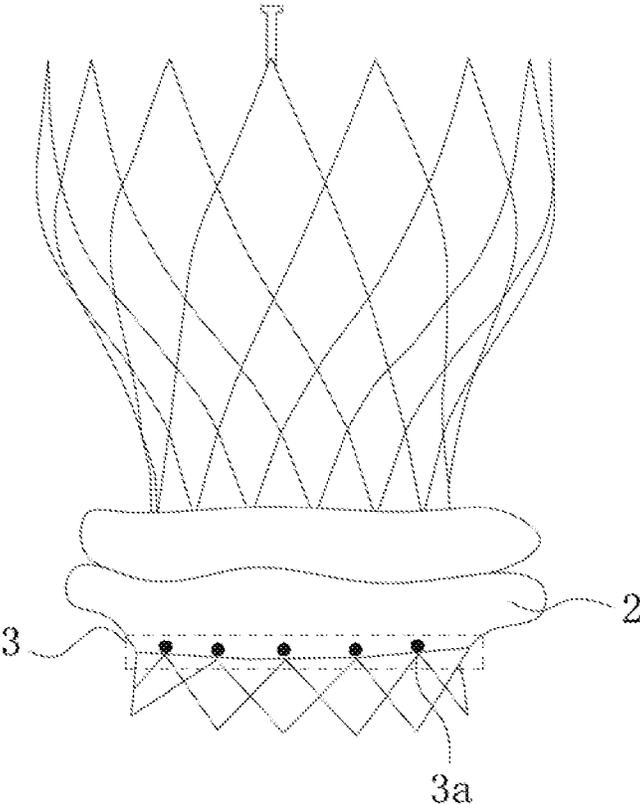


FIG. 9

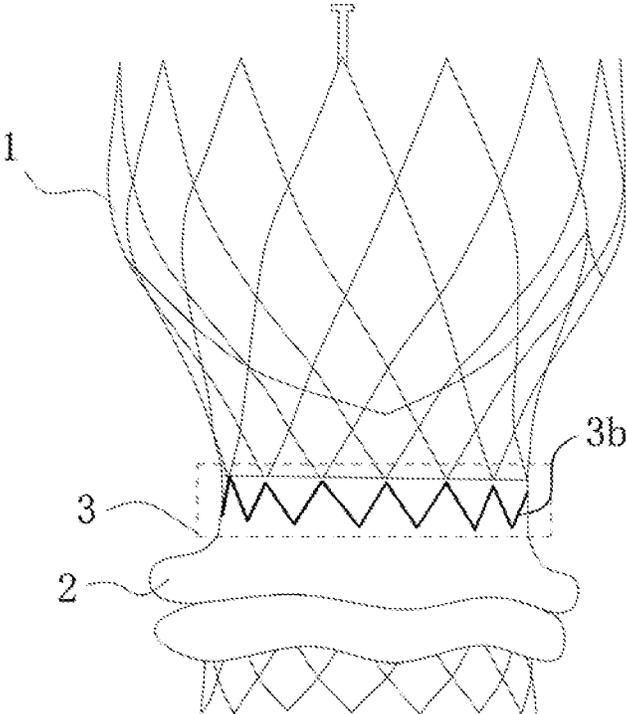


FIG. 10

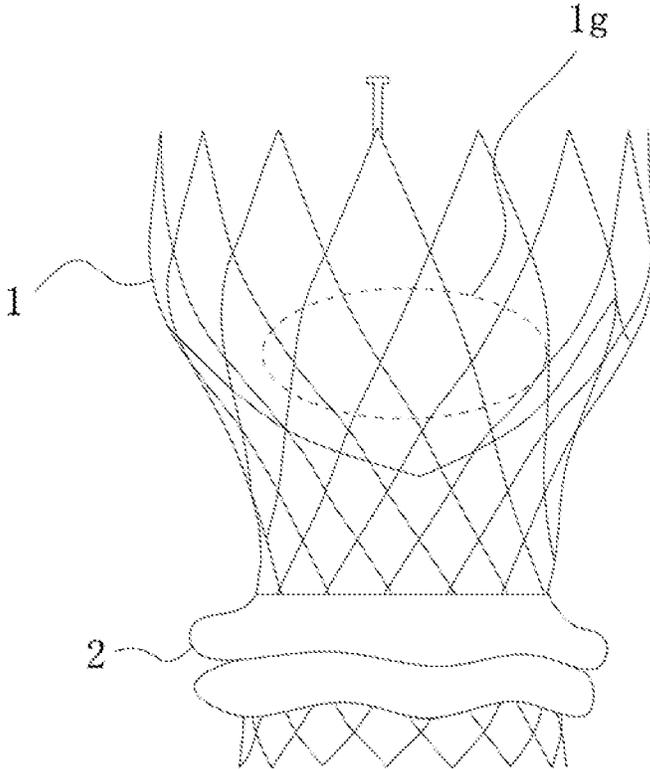


FIG. 11

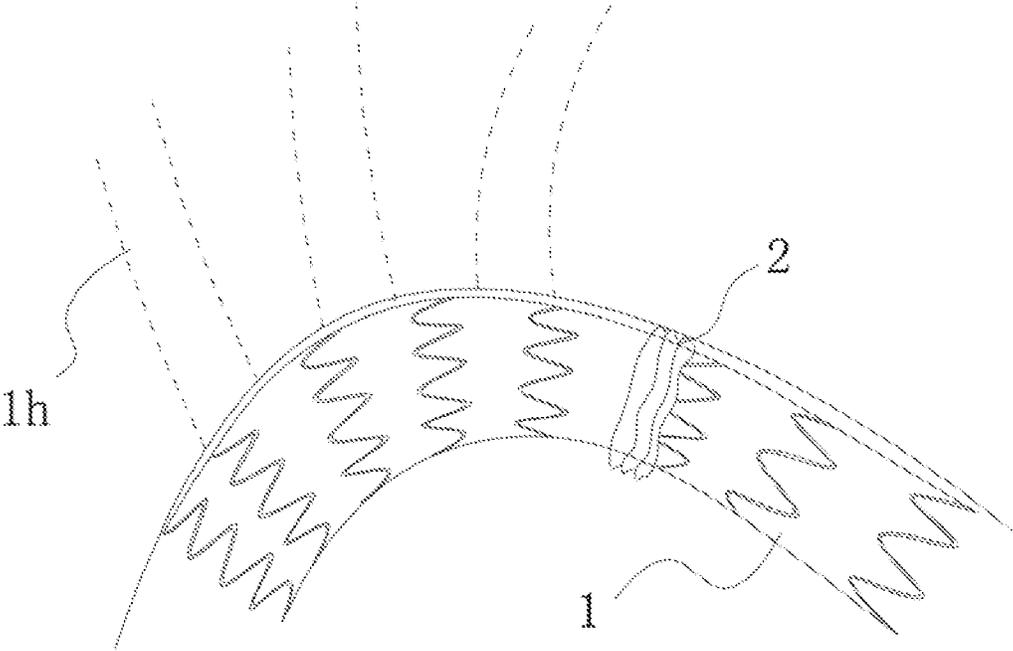


FIG. 12

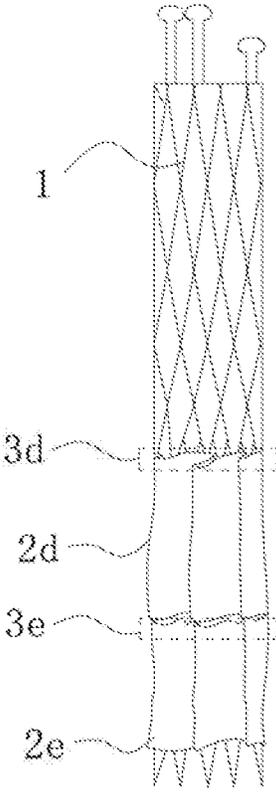


FIG. 13a

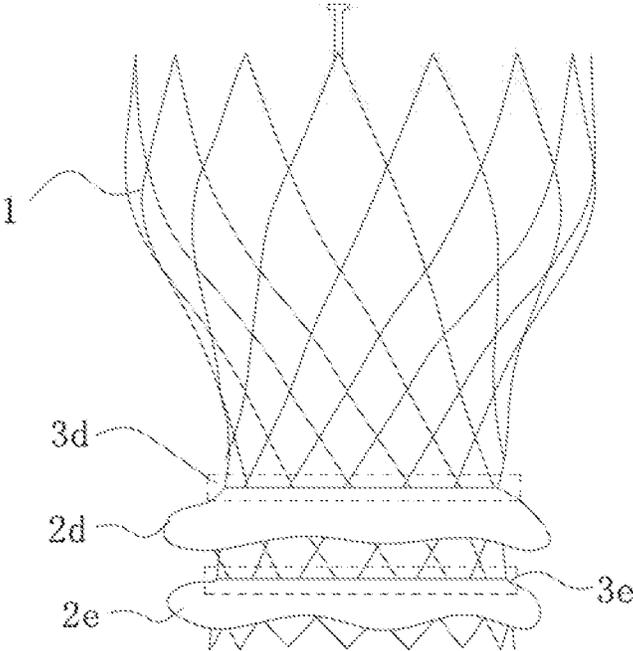


FIG. 13b

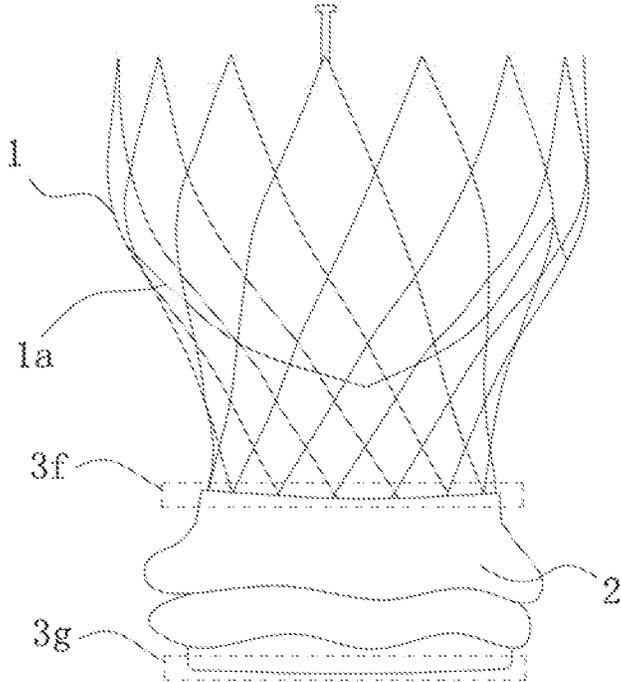


FIG. 14a

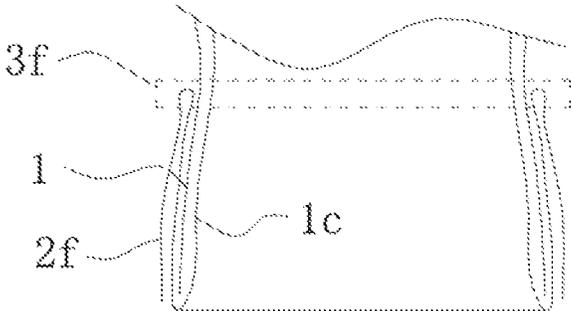


FIG. 14b

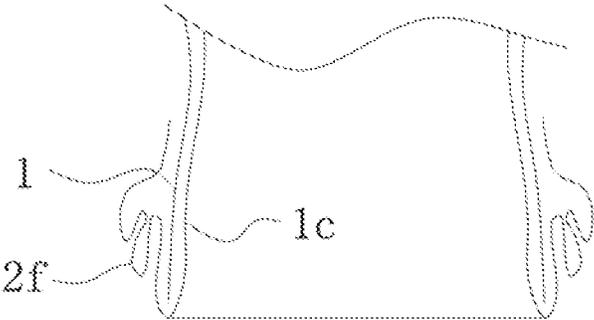


FIG. 14c

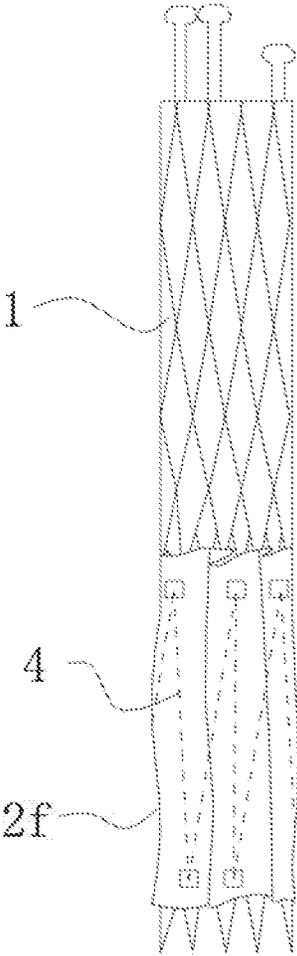


FIG. 14d

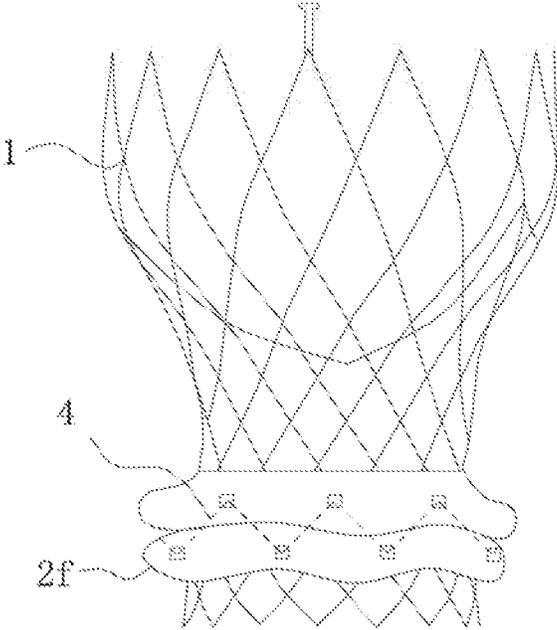


FIG. 14e

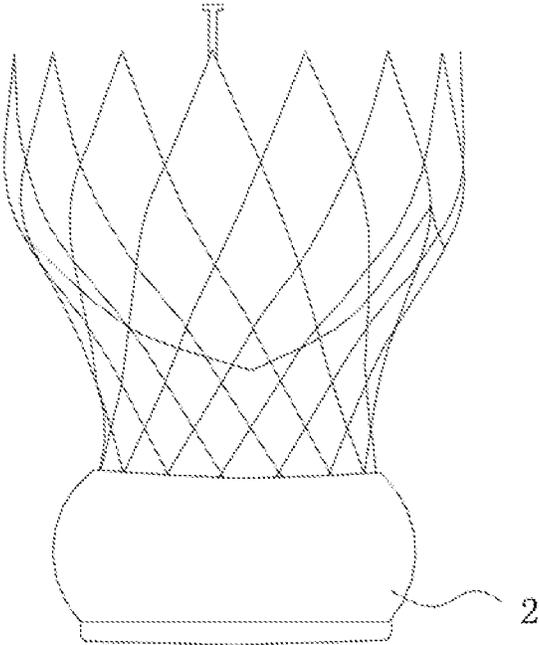


FIG. 14f

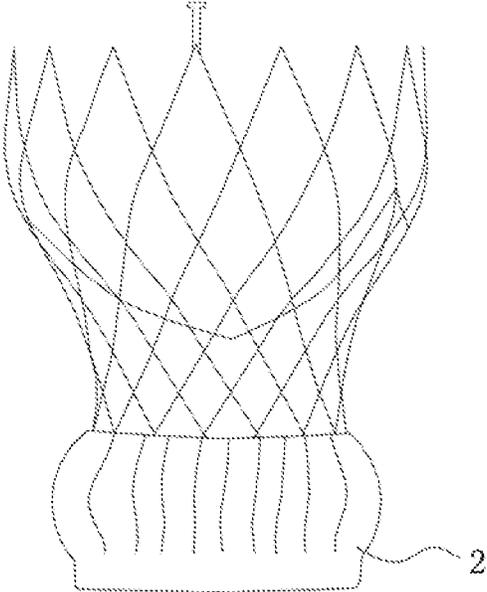


FIG. 14g

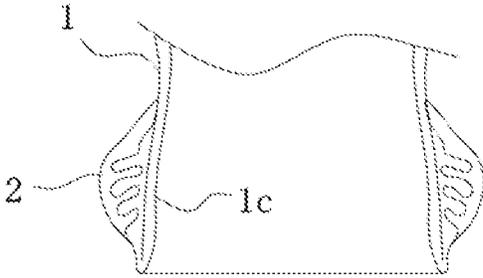


FIG. 14h

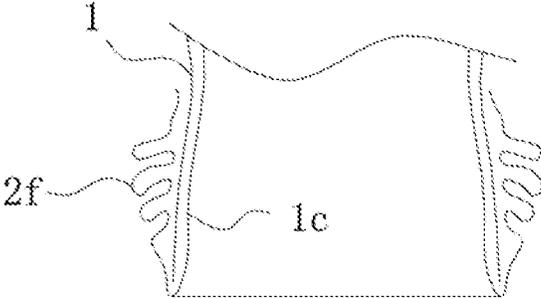


FIG. 14i

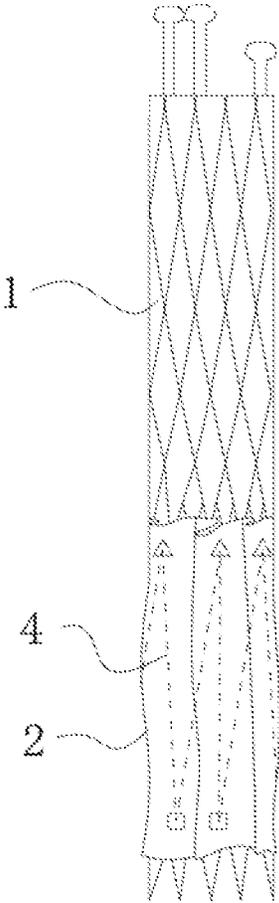


FIG. 15a

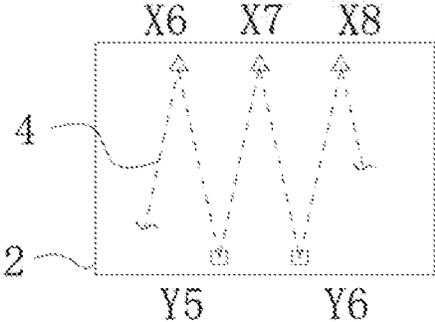


FIG. 15b

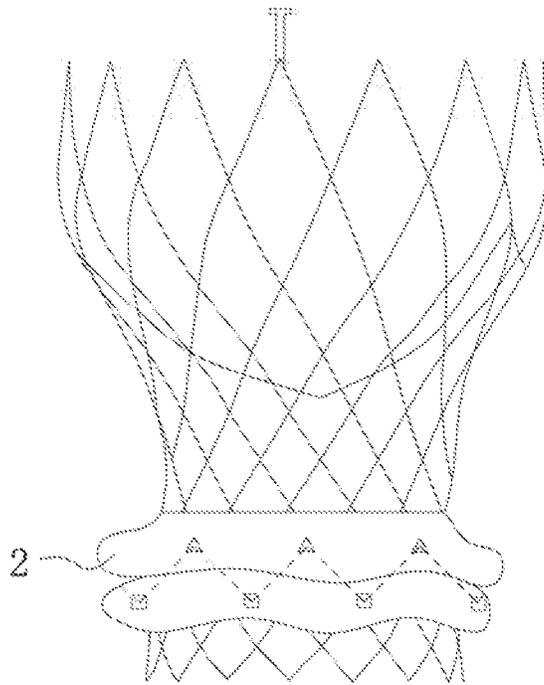


FIG. 15c

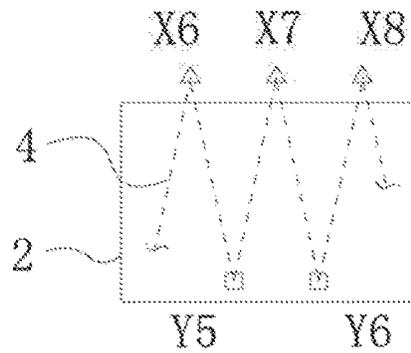


FIG. 16

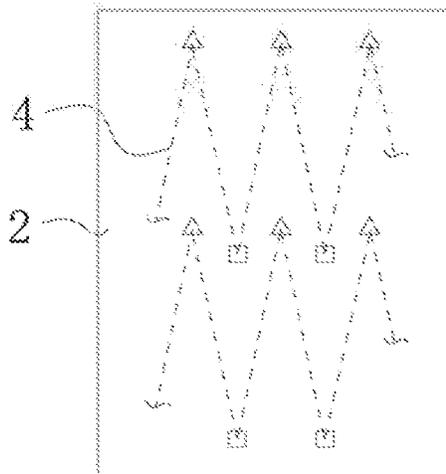


FIG. 17a

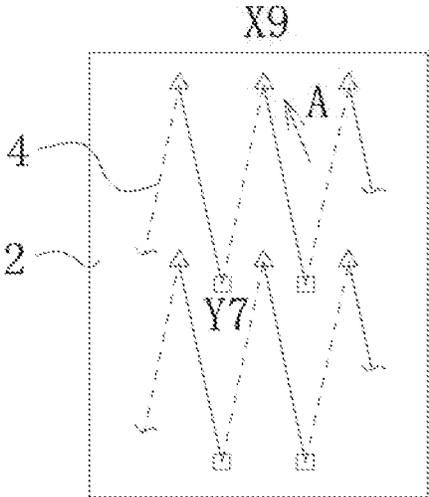


FIG. 17b

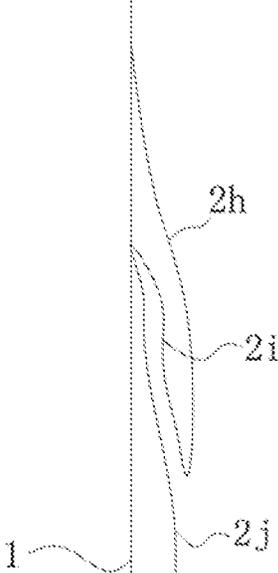


FIG. 17c



FIG. 17d

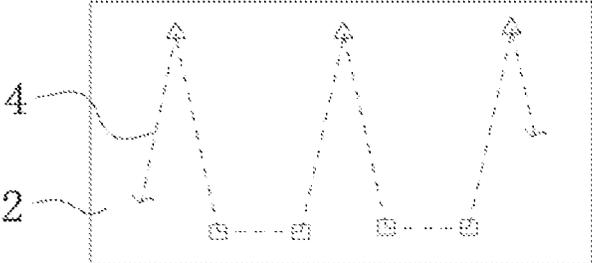


FIG. 18

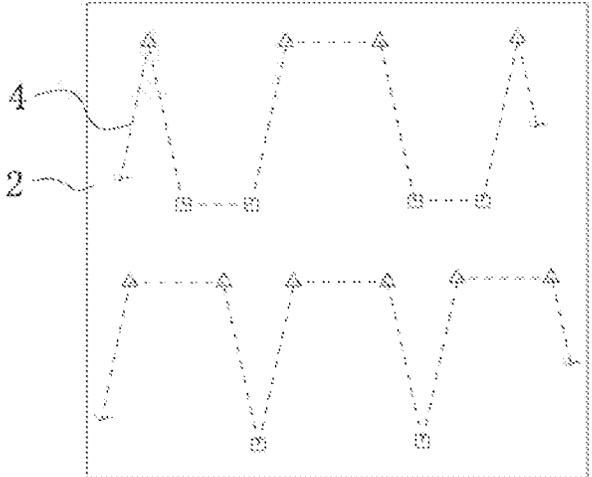


FIG. 19

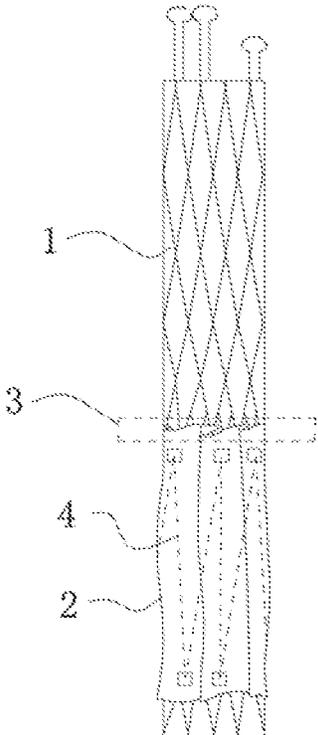


FIG. 20a

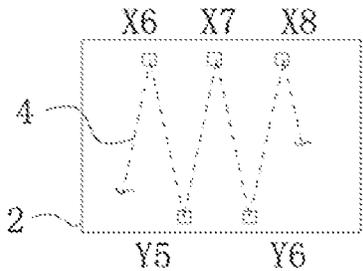


FIG. 20b

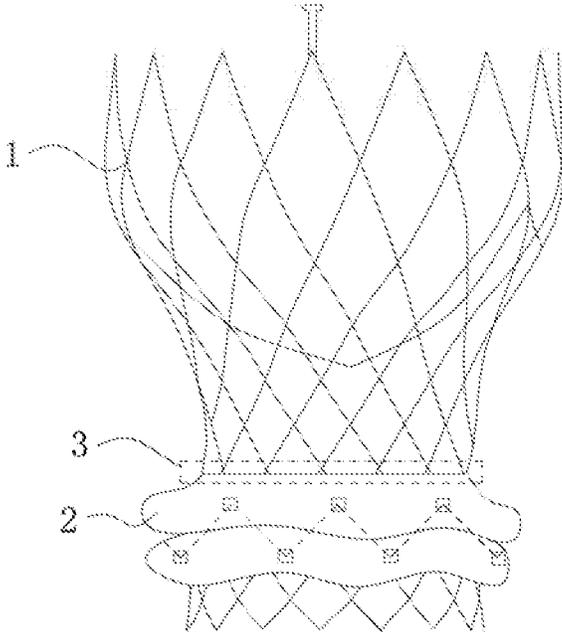


FIG. 20c

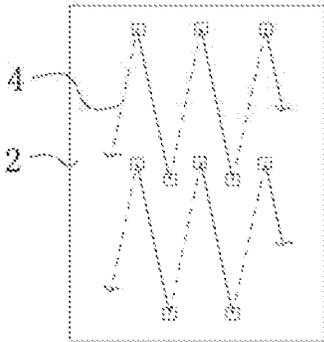


FIG. 21

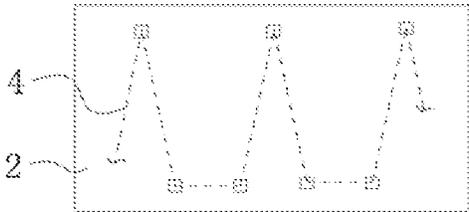


FIG. 22

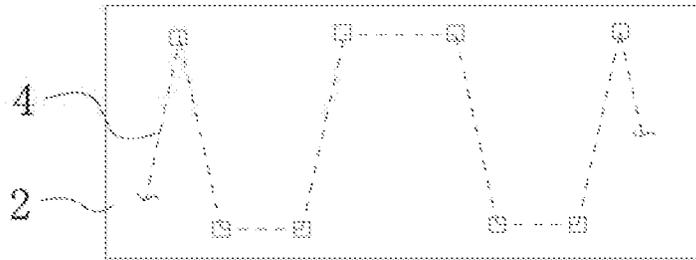


FIG. 23

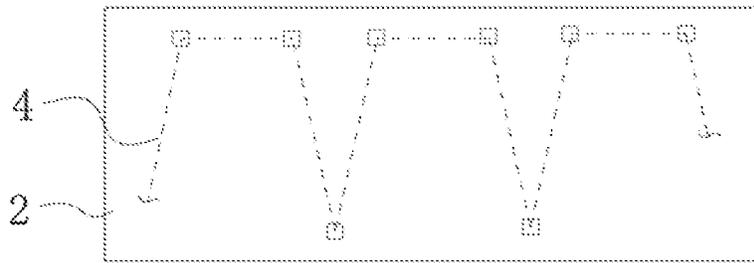


FIG. 24

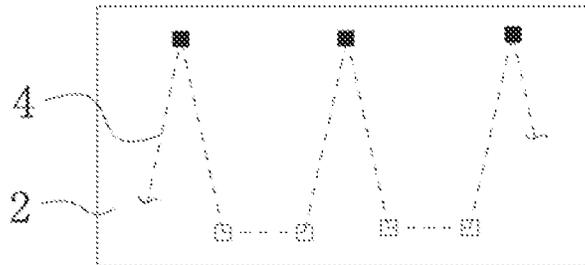


FIG. 25

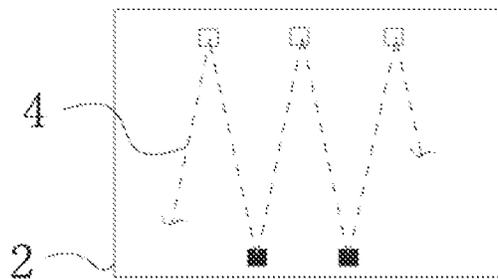


FIG. 26

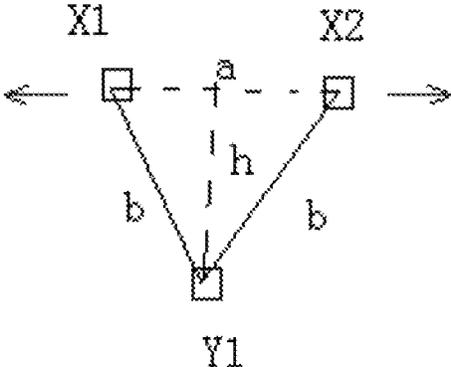


FIG. 27a

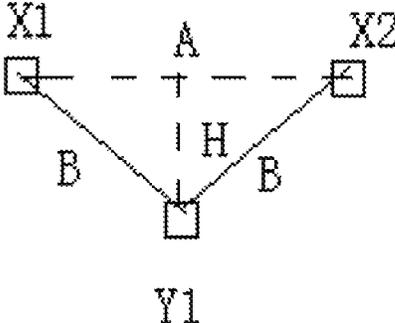


FIG. 27b

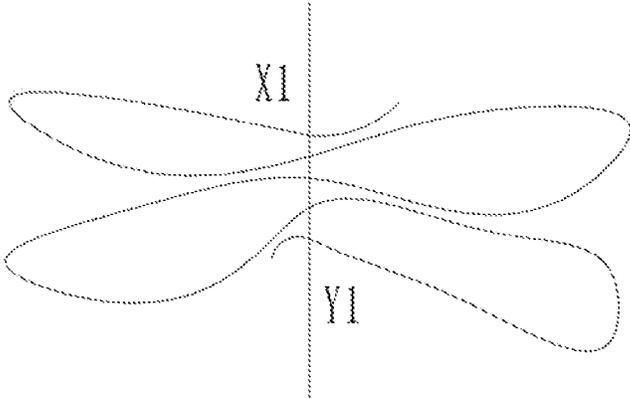


FIG. 27c

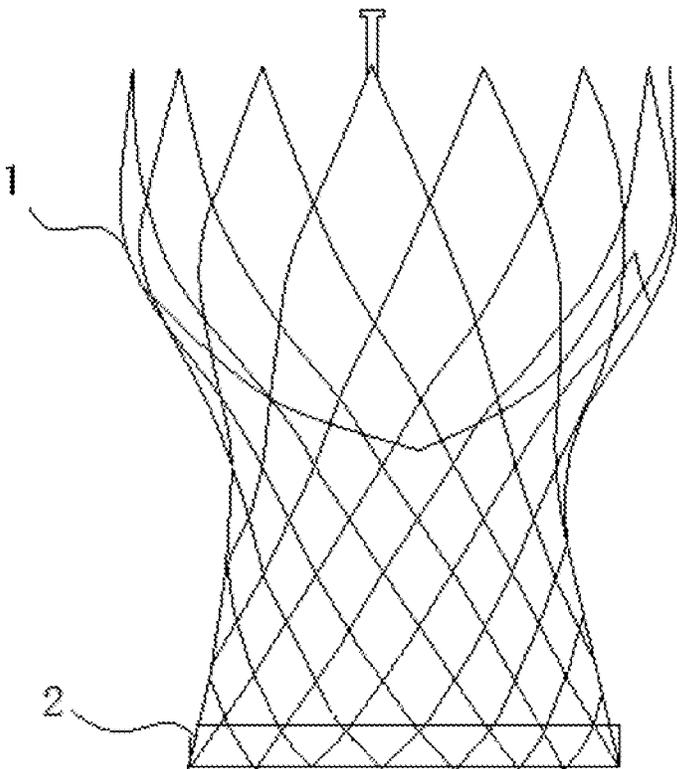


FIG. 28a

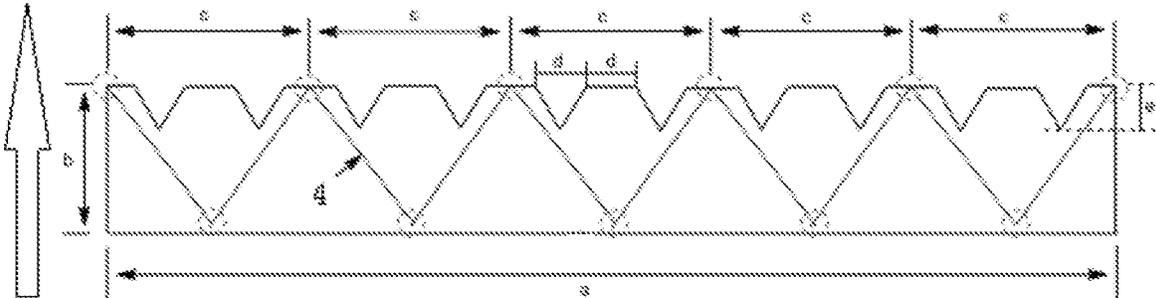


FIG. 28b

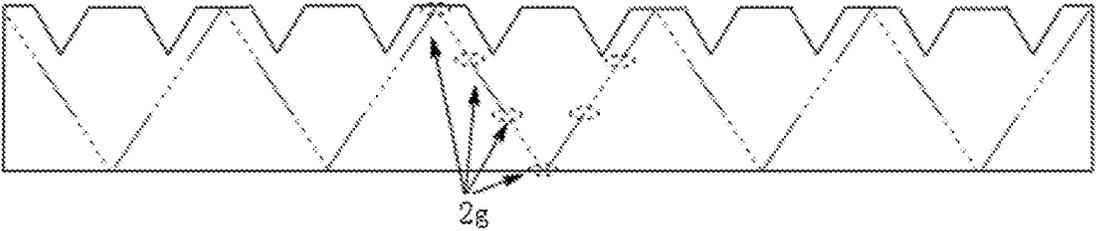


FIG. 28c

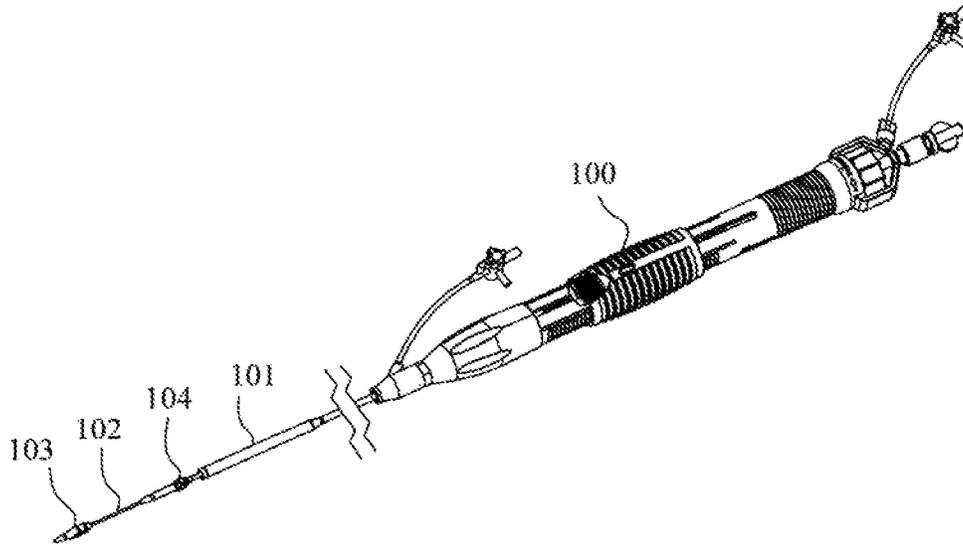


FIG. 29a

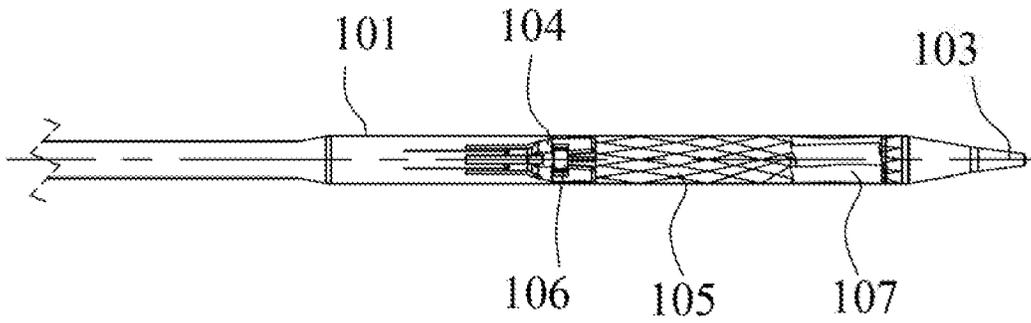


FIG. 29b

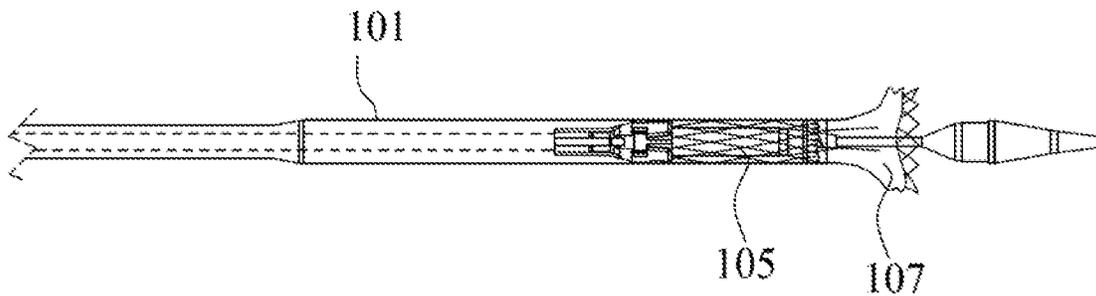


FIG. 29c

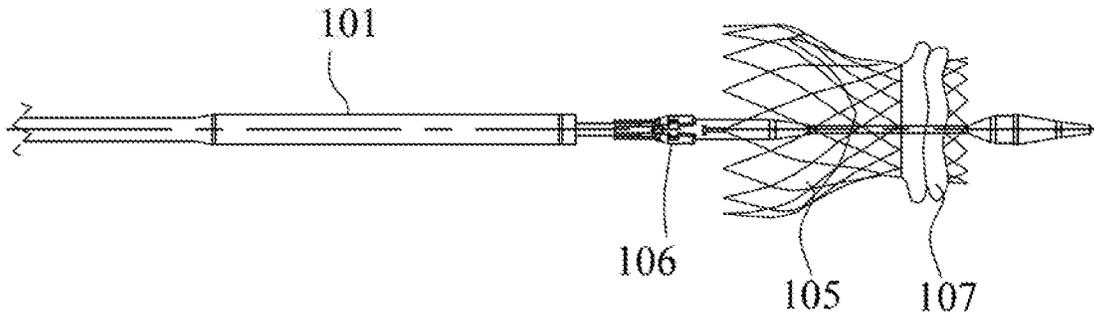


FIG. 29d

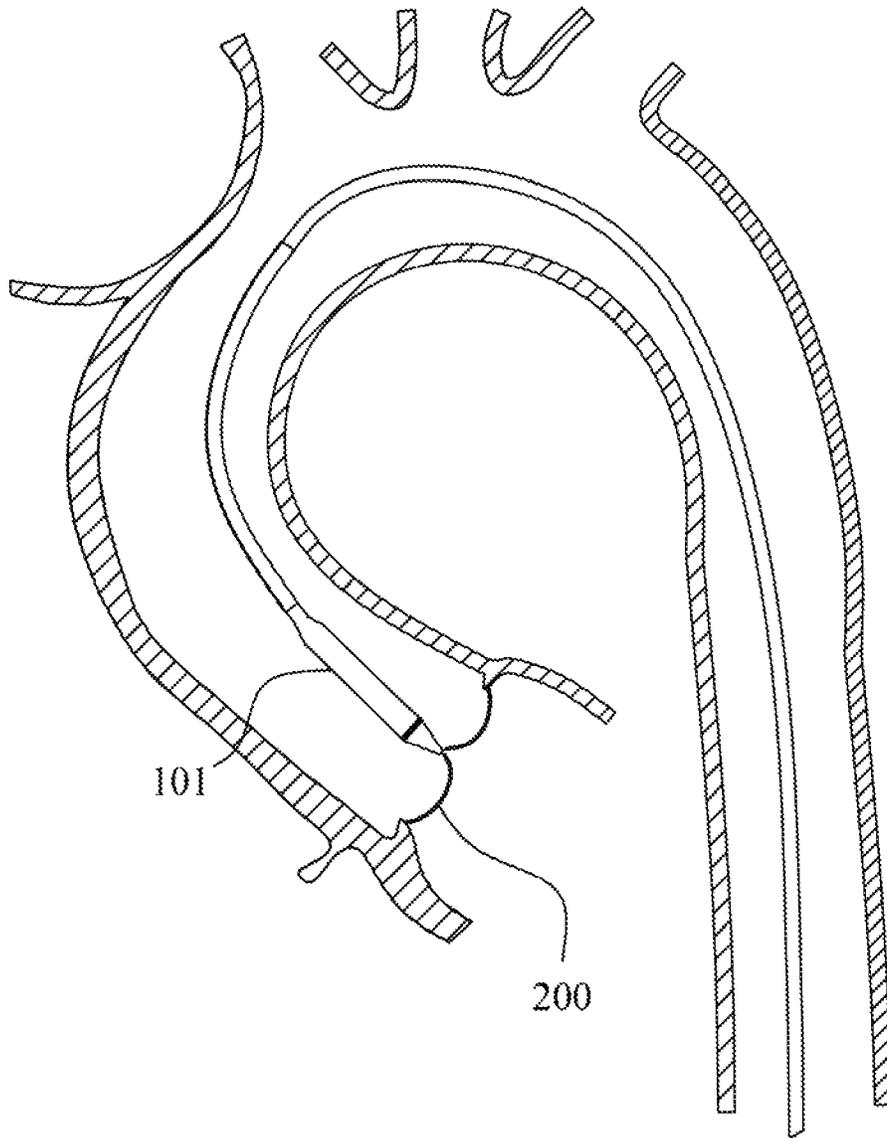


FIG. 29e

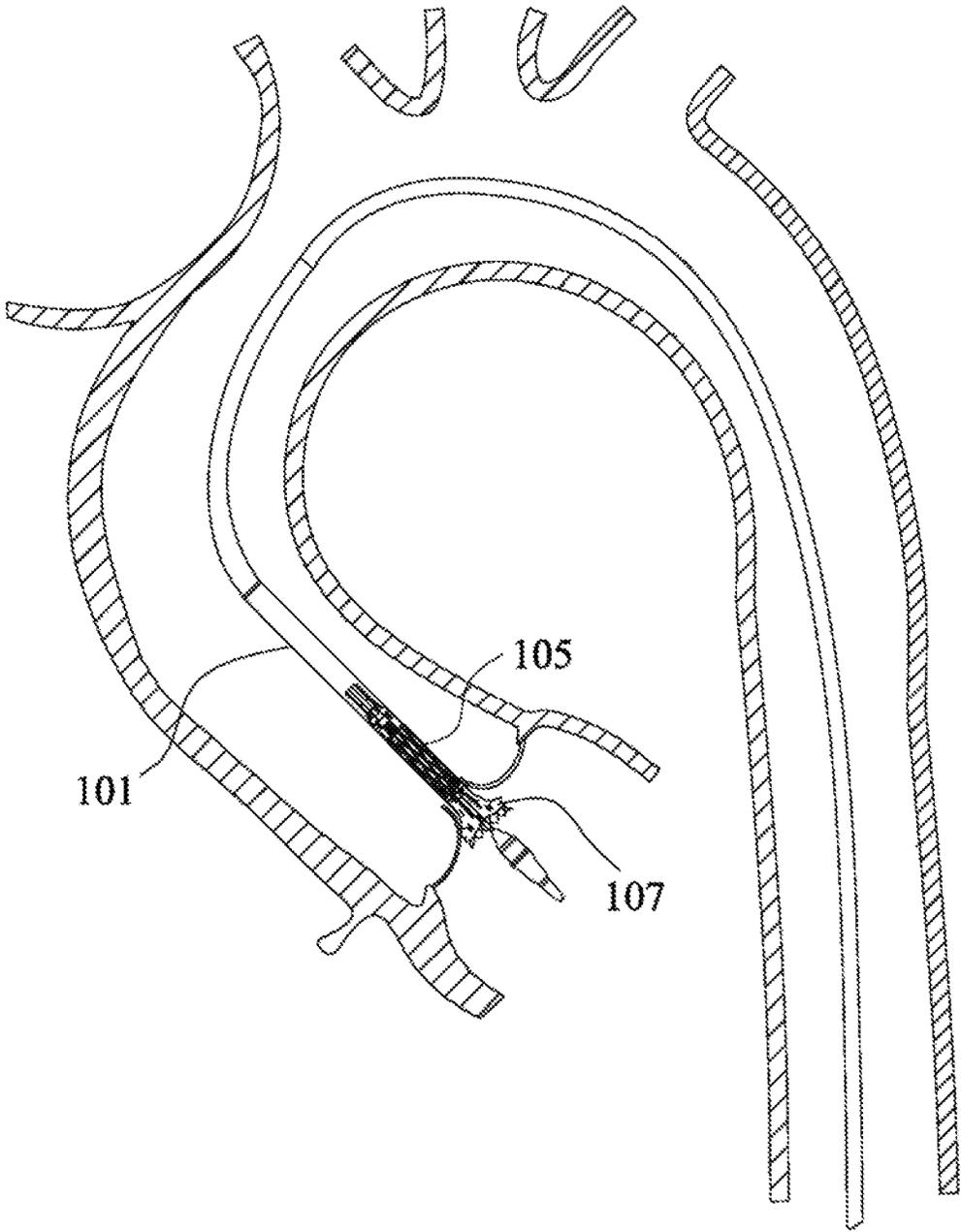


FIG. 29f

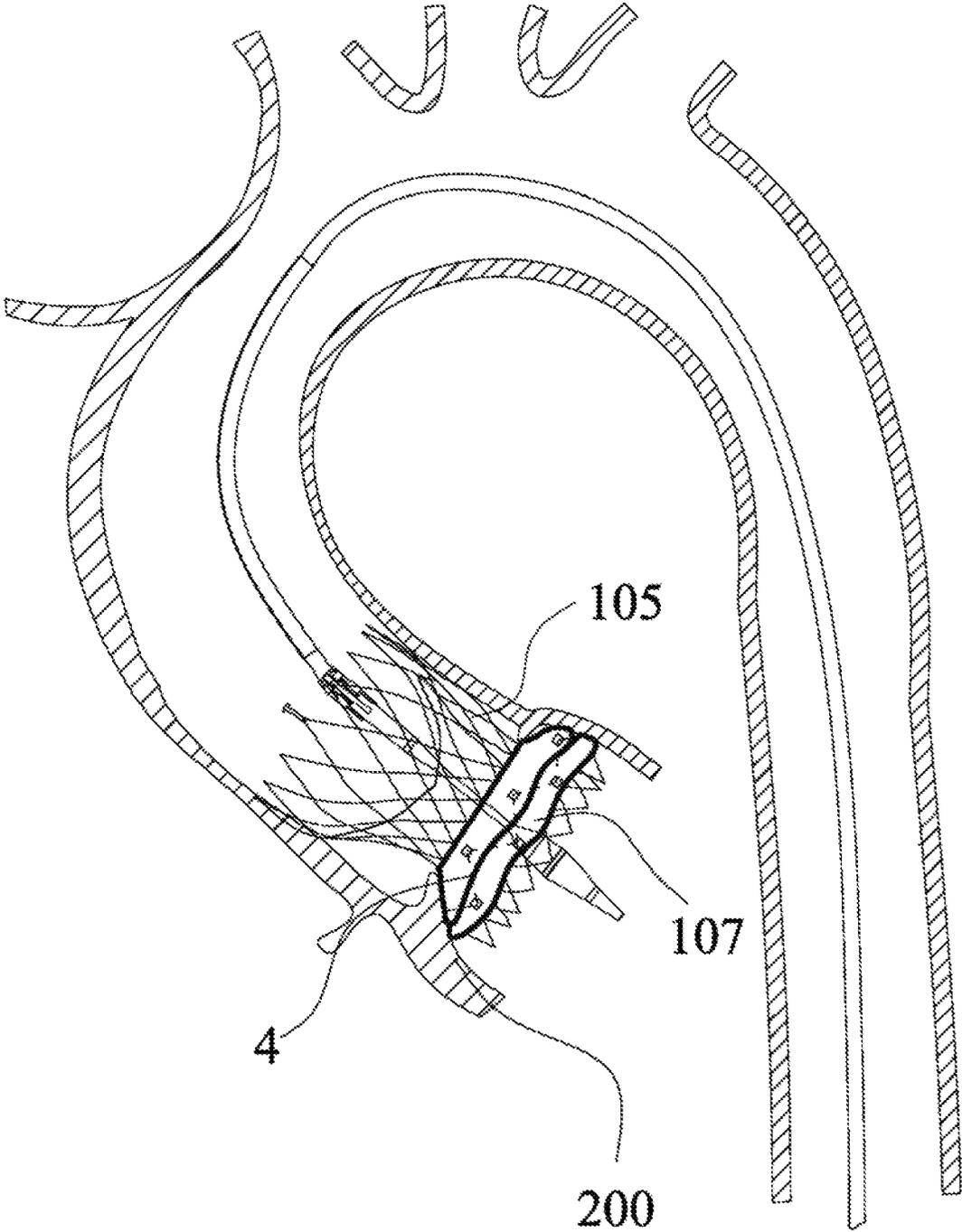


FIG. 29g

## STENT DEVICE WITH SKIRT FOLDS AND PROCESSING METHOD THEREOF, SKIRT FOLDING METHOD, AND HEART VALVE

### TECHNICAL FIELD

The present application relates to the technical field of medical apparatuses, and in particular, to an artificial stent apparatus for a heart, or a blood vessel.

### BACKGROUND

Since the 1970s, artificial heart valve replacement, as an effective treatment for end-stage heart valve disease, has saved millions of patients' lives. Artificial heart valve replacement is a revolutionary breakthrough in heart valve treatment technology, and has broad prospects.

Perivalvular leakage (PPL) is a serious and unique post-operative complication of valve replacement and is one of the common reasons which cause reoperations. The reason why PPL occurs is mainly related to the pathological changes of the annulus tissue such as degenerative changes, rheumatic or senile calcification, acute infective endocarditis invading the annulus or perivalvular abscess, mismatch in size between the artificial valve and the annulus, and prosthetic valve endocarditis.

Peripheral leakage occurs not only when implanting an artificial stent in the heart, but also in blood vessels or other body channels. For ease of description, perivalvular leakage is mainly taken as an example here.

The perivalvular leakage usually has the following adverse effects: (1) severe hemolysis, anemia, and progressively increased hemoglobinuria; (2) abnormal changes in hemodynamics, failure of heart function or even heart failure caused by large orifices for perivalvular leakage, with poor symptoms and signs improvement after conservative treatments; (3) infective endocarditis concurrent even with a small orifice for perivalvular leakage; and (4) bioprosthetic valve failure concurrent with a perivalvular leakage.

At present, some research work has been done on the prevention of perivalvular leakage, at home and abroad. However, the perivalvular leakage cannot be decreased to a rate below 5% during transcatheter replacement at this time. Therefore, further research work is needed on how to reduce the perivalvular leakage.

At present, the main method of transcatheter bioprosthetic valve implantation for the treatment of heart valve disease is to compress an artificial heart valve into a delivery device, which delivers the valve to a lesion site of the heart through blood vessels, and then release the artificial heart valve to replace the diseased native valve. Typical heart valves include balloon expandable valves or self-expanding artificial heart valves. The self-expanding artificial heart valve generally includes a meshed stent made of a shape memory metal material, and a valve sewn in the stent which opens unidirectionally. During implantation, the stent expands itself and fits the diseased annulus as much as possible. Although the perivalvular leakage can be reduced to a certain extent, the perivalvular leakage and peripheral back flow will still occur more or less to some patients who have blood vessels with irregular inner walls due to autocalcification. The stent of the balloon expandable valve is usually made of medical stainless steel. During implantation, the stainless steel stent is expanded by the balloon and fits the diseased annulus as much as possible.

The typical balloon expandable valve or self-expanding valve expands the inner wall of the blood vessel only by the

radial support force of the metal stent. For patients who have blood vessels with regular inner walls, an appropriate stent may be chosen to substantially fit the inner walls of the blood vessels by valve selection, which can reduce perivalvular leakage to a certain degree. However, for patients who have blood vessels with irregular inner walls caused by calcification, perivalvular leakage will occur more or less. A large number of clinical studies indicate that it is difficult to reduce the perivalvular leakage to a rate below 5%, so the risk of perivalvular leakage still exists. At present, once a patient suffers from perivalvular leakage, it can only be solved by measures such as repair and valve replacement, which results in a high risk for surgery and thus to the patient's life.

Although there have some typical solutions, all of these solutions have certain shortcomings. For example, perivalvular leakage may be prevented by providing an annular pocket around the periphery of a stent, which would be filled with back-flow blood. However, it is likely to generate thrombus in the annular pocket, and there is a risk that the thrombus may fall off.

There are also some solutions which block perivalvular leakage by forming an annular protrusion protruding radially with a water-absorbing expansion material on the outer periphery of the stent, while there is also a risk that the water-absorbing expansion material may fall off, which results in potential danger.

There are also some solutions provided with a flexible film at an inflow end of the stent, wherein the flexible film is located at an axial side of the stent before being released, and rolled up or folded up near the inflow end of the released stent to form an annular protrusion protruding radially so as to block perivalvular leakage.

However, as the flexible film is provided at the axial side of the stent before being released, which makes the entire length of the resulting stent apparatus too long, thereby resulting in higher requirements for a delivery system. More importantly, in order to achieve the rolling or folding of the flexible film, an additional dragging mechanism must be provided, which is controlled by an operator and thus increases the complexity and difficulty of control. Alternatively, a metal member may be provided, which, based on the characteristic of having a preset shape thereof, drives the flexible film to roll up or fold up after being released in the human body. However, the metal member makes the structure of the stent more complicated, and brings additional risks. Furthermore, under the influence of the space outside of the stent, it is difficult to pull the flexible film to the desired position. Therefore, the effects are not satisfied.

### SUMMARY

The present disclosure provides a stent apparatus with a self-folded skirt, which forms a peripheral leakage occluder by stacking a flexible skirt around an outer periphery of a released stent. More importantly, the flexible skirt is driven to be stacked by a deformation of the stent itself during release; that is, the flexible skirt operates in cooperation with the deformation of the stent, without requirements for additional control and also avoiding the use of metal parts. The stent apparatus of the present disclosure is able to seal the outer periphery of the stent in a flexible manner, with safe operation and convenient processing.

A stent apparatus with a folded skirt, comprising a stent, wherein, the stent apparatus is further provided with at least one flexible skirt, which has:

3

an unfolded configuration, in which the skirt is axially unfolded and surrounds an outer periphery of the stent before being released;

a stacked configuration, in which the skirt is driven by a deformation of the stent during release and folded and stacked in an axial direction of the stent after being released and forms an annular peripheral leakage occluder.

The stent itself of the present disclosure may be any of various known stents, and the main improvement of the present disclosure is the inventive skirt located around the outer periphery of the stent. Individual configurations of the skirt are configured to adapt to a released stent and an unreleased stent, respectively. The stent is provided in a radial compressed configuration after being loaded into a delivery system, i.e., a configuration before being released. Correspondingly, the skirt is provided in the unfolded configuration. In order to facilitate the travel of the stent in the human body, the stent should be compressed as much as possible. Correspondingly, the skirt is unfolded in the axial direction. The present disclosure also differs from the prior art in that the skirt surrounds around the outer periphery of the stent before being released, at least with most of the skirt surrounding around the outer periphery of the stent, rather than being located at an axial side of the stent. Since the skirt is thin and has a good flexibility, it is able to conform very well to the outer periphery of the stent.

After being delivered into the human body with the delivery system, the stent is released by withdrawing the sheath of the delivery system. The stent starts to be released and gradually expands radially. After the release is completed, the shape of the stent remains relatively stable and fixed. During the release of the stent, the radial expansion of the stent is accompanied by changes in the circumferential direction, i.e., the perimeter increases.

The stent after being released is stably placed at the corresponding lesion site. Correspondingly, the skirt assumes the stacked configuration. The radial expanding of the stent will drive the skirt to be axially folded and stacked, thereby thickening the skirt around the outer periphery of the stent and forming the annular peripheral leakage occluder.

The skirt may be driven by the deformation of the stent being released using various techniques. For example, the skirt may be driven to be axially stacked directly by the stent expanding outwardly, or the skirt may be driven to transform into the stacked configuration by a driving mechanism which operates in cooperation with the deformation of the stent, or the skirt may be driven by a combination of the aforementioned techniques, or by a further combination with other factors such as the blood flow in the human body or the shape of the stent or the skirt.

When axially unfolded, the skirt in the unfolded configuration minimizes the radial dimension. In addition, the skirt will be axially unfolded by the outer sheath during load. The term axially unfolded described in the present disclosure should not be strictly limited to the meaning that the skirt "must" be axially unfolded and straightened, but should be interpreted as the skirt "may" be axially unfolded due to the structure of the skirt and the position or connection relationship between the skirt and the stent.

There is no strict limit to the specific stacked structure of the stent during axial folding and stacking, provided that axially folding the skirt will at least cause a thickening of the skirt in the radial direction for sealing the peripheral leakage.

Many alternative or preferred arrangements are further provided only for additional or preferred implementation, without any limitation to the above general solution. With-

4

out conflict in technique or logic, the arrangement may be combined with the above general solution alone or multiple arrangements may be combined with each other. Optionally, the skirt transforms into the stacked configuration under the radial deformation of the stent during release.

As one of the techniques for driving the skirt to transform into the stacked configuration, the deformation of the stent being released directly acts on the skirt and supports the same. The stent is not released instantaneously, but gradually. One end of the stent which is first released radially expands first and forms a flared configuration, and the deformation gradually transfers to the other end of the stent which is released later with the stent gradually falling off the delivery system. During this process, the gradually formed flared section drives the skirt to expand and guides the skirt to be folded and stacked axially. In addition, in the case where the end of the stent which is released first faces opposite to the direction of the blood flow, the impact on the skirt from the blood flow can also urge the skirt to be axially folded.

Optionally, the skirt is made of a flexible material and constrains around the outer periphery of the stent in a released configuration.

The skirt made of an elastic material is easy to be axially folded, and when it constrains around the outer periphery of the stent after being released, the corresponding stacked configuration thereof can be stably maintained, thereby avoiding an axial self-unfolding of the skirt and a failure to block the peripheral leakage.

Optionally, the at least one skirt comprises one or more skirts which are arranged one above the other in the axial direction, and the skirts in the stacked configuration form respective peripheral leakage occluders.

Since the axial deformation of a single skirt is limited, more skirts may be provided and arranged in the axial direction. Since the skirt and the stent both have tubular shapes, and the skirt is arranged at the outer periphery of the stent, the axial direction referred to in the present context can be regarded as either one of the axial direction of the stent and the axial direction of the skirt unless otherwise specified. The other orientations or directions, such as the radial direction and/or the circumferential direction, can be similarly interpreted.

Optionally, individual skirts generally float around the outer periphery of the stent and adaptively form peripheral leakage occluders at respective positions.

The term float means that the skirt and the stent are not fixedly connected to each other. Although the skirt may surround and constrain around the outer periphery of the stent with its elasticity, it is not fixedly connected thereto by a common technique such as by a connecting element or stitching. The blood flow in the human body allows the peripheral leakage occluders formed by the skirts to adapt to the respective positions themselves. It should be noted that the term float also means that the skirts or the formed peripheral leakage occluders cannot fall off the stent.

Preferably, a flexible limiting string is provided between the stent and the skirt.

The flexible limit string on the one hand is able to adapt to the axial movement of the skirt, and on the other hand prevents the skirt from falling off from the stent, thereby further improving safety.

The stent of the present invention may be a known stent, for example, with a generally cylindrical shape, and being processed by braiding or cutting. It has a meshed structure with a plurality of grids arranged regularly or partially combined with other structures having different shapes.

5

The stent may be used in the aorta, aortic valve, pulmonary artery, pulmonary valve, mitral valve, tricuspid valve, occluding device, general blood vessel or the like. The shape of the stent and the presence of the coverage membrane may be adaptable based on the prior art as required.

Preferably, one section of the stent in the axial direction is configured as a flared driving structure that is configured to drive the skirt to be folded and stacked.

The stent may take a flared configuration during the release. In order to further ensure that the skirt can be folded and stacked in the axial direction, the stent itself may also form a flared driving structure at a section thereof corresponding to the skirt. In addition, the guidance of the flared structure functions to maintain the skirts in the stacked configuration after the stent is completely released without loosening in the axial direction, so as to ensure the function of the peripheral leakage occluder.

Preferably, the flared driving structure is located at a middle portion of the stent in the axial direction, or adjacent to axial ends of the stent.

Preferably, the flared driving structure is adjacent to an axial end of the stent, and is flared at the corresponding end.

Preferably, the flared driving structure is adjacent to the blood inflow end of the stent, and the closer to the blood inflow end, the wider the opening of the flared driving structure. An appropriately orientated flared driving structure may operate in cooperation with the blood flow to push the skirts to axially stack. A blood flow from the wide opening to the narrow opening has a function in compliance with the guidance of the flared driving structure. It is further preferred that the wide opening side of the flared driving structure is released first, and the narrow opening side is released later, which works on the skirt in cooperation with the flared structure of the stent during the release, so as to guide the skirt to be axially stacked and to maintain the skirt in the stacked configuration.

Preferably, the flared driving structure extends to the distal end of the stent which is to be released first.

The flared driving structure extending to the distal end of the stent which is to be released first has the following advantages: when the stent starts to be released, the flared structure thereof presents clearly, and in addition, the axial limit to the peripheral leakage occluder may be steadily maintained.

Optionally, the generatrix of the flared driving structure is a straight line, a smooth curved line, or a combination of a straight line and a curved line.

The shape of the generatrix determines the extension of the flared mouth and is not strictly limited in the present invention. The generatrix may be a single straight line or smooth curved line, or a combination of a straight line and a curved line, provided that a generally flared structure is formed and the flared driving structure should at least function at the distal end of the skirt to be released first.

Preferably, one axial side edge of the stent has a sharp angled structure, and before the stent is released, the corresponding side of the skirt does not extend axially beyond the tips of the sharp angled structure.

When the stent is being released, the distal end which is to be released first will turn outwardly. If the skirt in the unfolded configuration covers the side with the tips, the distal end of the stent to be released first may snag the inner side of the skirt or even pierce the skirt, which would prevent the skirt from being axially folded. The typical stents are generally in meshed structures, with end nodes of grids or sharp tips at the distal end to be released first, which are likely to snag on the skirt during release.

6

Therefore, it is preferred that at least a part of the stent is released at the earliest point and then works on the skirt so as to automatically guide the skirt to be stacked.

Before the stent is released, the corresponding side of the skirt may be unfolded in a single layer, rolled inwards/outwards, folded or stacked. In any event, it is preferred that the axial edge of the skirt does not extend beyond the tips of the sharp angled structure at the corresponding side.

Preferably, before the stent is released, at least a portion of the distal end of the stent to be released first is exposed outside the skirt, and the exposed portion is released before the skirt.

Preferably, a section of the stent in the axial direction is a flared driving structure that drives the skirt to be folded and stacked, and at least a portion of the flared driving structure is configured as said exposed portion.

It is apparent to have a coordinative effect by releasing the stent before the skirt in combination with said flared driving structure.

In order to facilitate the stacking of the skirt, at least to prevent the skirt from being "snagged" during the release of the stent, it is further preferred that an axial end of the stent has a smooth curved edge. Due to such configuration, the corresponding side of the skirt may extend axially beyond the stent before the stent is released.

For example, the edge of the distal end of the stent to be released first is formed by a plurality of curved segments connected one after the other, and the skirt extends axially beyond the distal end of the stent to be released first. The curved structure would not pierce or snag the skirt, so it is allowable for the skirt to extend axially beyond the distal end of the stent to be released first in such a way that a peripheral leakage with higher profile and larger volume may be formed by the longer skirt, thereby improving the sealing effect.

Preferably, at least a portion of the skirt is fixed on the stent.

The term fixed referred to here is relative to the term floating mentioned above. It means that at least a portion of the skirt remains in a fixed position relative to the stent and is free of influence of external factors such as blood flow, which functions to control the position of the resulting peripheral leakage occluder.

Preferably, a portion of the skirt in the axial direction is configured as a fixing band, which is stitched on the stent.

The skirt may be fixed on the stent in a known manner by means of which the valve can be fixed on the stent, such as stitching. In order to ensure the fixation of the skirt on the stent, the skirt is usually stitched for a perimeter of the stent.

Optionally, the fixing band is stitched continuously or discontinuously in a circumferential direction.

The expression stitching continuously means that the stitch line threads through the stent and the skirt repeatedly with dense stitch points. The expression stitching discontinuously means that fewer stitching portions are provided, for example, with 3 to 10 stitching portions for a perimeter of the stent.

Preferably, in the case of stitching discontinuously, the stitching portions are evenly arranged in the circumferential direction, with force evenly applied and stress concentration avoided.

Preferably, the stitch course of the fixing band extends in the circumferential direction, or undulates in the axial direction while extending in the circumferential direction.

Undulating in the axial direction may depend on the structure of the stent or the structure of the skirt. For example, the fixing band is located on the edge of the skirt,

with an non-smooth edge and thus having an undulated configuration. The strength of the connection between the skirt and the stent may also be considered.

Preferably, the stent has a meshed structure with grids, and the fixing band is fixed on the stent through a stitch line stitching on the edge of the grids.

In this solution, the stitch line extends along the grids according to the structure of the meshed stent to ensure the strength of the connection, which can avoid loosening after the release or during loading into the delivery system under a large friction.

Optionally, there is one or more fixing bands arranged in the axial direction.

The skirt is fixed to the stent only at the fixing band, and the remaining portion of the skirt is movable relative to the stent. In particular, at least a portion of the skirt is movable and foldable axially. In the case that there is only a single fixing band, the remaining portion of the skirt floats around the outer periphery of the stent.

Preferably, a single fixing band is located at the middle portion or an end of the skirt in the axial direction.

In the case that there is only a single fixing band, the larger portion of the skirt is a floating section and thus there will be a larger portion which is stackable in the axial direction. The fixing band is provided adaptively at the desired position of the peripheral leakage occluder, and the remaining floating section will move towards the fixing band during the axial stacking.

Preferably, at least one section of the skirt in the axial direction is configured as a floating section around the outer periphery of the stent, and the floating section is folded axially in the stacked configuration of the skirt. Both axial sides of the floating section are configured as fixing bands. Alternatively, one axial side of the floating section is configured as a fixing band, and the other axial side of the floating section is floatable.

For example, the top edge of the skirt is fixed on the outer periphery of the stent, and the lower section of the skirt floats around the outer periphery of the stent. Alternatively, the bottom edge of the skirt is fixed on the outer periphery of the stent, and the upper section of the skirt floats around the outer periphery of the stent.

Preferably, a proximal end of the skirt which is to be released later is fixed on the stent, and a distal end of the skirt which is to be released first floats around the outer periphery of the stent.

The distal end of the skirt which is to be released first is provided in a floating manner and will be accompanied by axial stacking during the release, which facilitates the coordinative guidance of the stent and the blood flow.

In order to facilitate the loading of the stent in a compressed configuration into the delivery system, such as into a sheath, it is preferable to load the side with the fixing band first, and then load the floating side, which makes the loading process smoother, otherwise the skirt may be folded during loading, and the radial dimension thereof may increase, thereby reducing compliance thereof.

Since the loading and the release are generally opposite processes, loading the side with the fixing band first also means that the proximal side of the skirt to be released later is fixed on the stent.

Preferably, during release of the stent, at least a part of the skirt constrains the stent, and the skirt is driven to be pulled axially with the stent further released.

The release of the stent is developed gradually. During this process, it is necessary for the outer periphery of the

stent to contact the skirt and produce an expanding force, so that the skirt can be pulled axially.

Preferably, before the stent is released, the skirt in the unfolded configuration has a folded structure in a circumferential direction.

Since the stent before being released has a low profile, the skirt may be attached to the outer periphery of the stent in a relatively flat manner due to the folded structure in the circumferential direction. After the stent is released, the circumferentially folded structure is unfolded due to the radial expanding of the stent.

Optionally, before the stent is released, the skirt in the unfolded configuration is generally unfolded in a single layer along the axial direction of the stent, or has a pleated structure.

Extending in a single layer contributes to reducing the radial dimension so as to facilitate the loading and delivery. The pleated structure occurs mainly due to the fixing bands provided at both axial ends of the floating section, so it cannot be unfolded in a single layer. However, the pleated structure facilitates the control of the position of the peripheral leakage occluder, and may also form a double-layered structure. The peripheral leakage occluder may be further expanded radially by filling with filler or blood into the double-layered structure, thereby improving the sealing effect. In order to solve the problem of the increased radial dimension, the shape of the stent may be further improved, such as by providing a meshed structure with grids provided more sparsely to synergistically reduce the radial dimension.

Preferably, the stent is provided with a valve and/or a coverage membrane.

As further preferred, the skirt and the valve and/or the coverage membrane are made of same material.

The stent may be provided with a valve and/or a coverage membrane according to its particular application (i.e., the lesion sites). The skirt has to be capable of being folded and stacked, so the skirt is made of flexible material and is at least axially deformable. Various typical valves, such as porcine pericardium or the like, may meet this requirement. In addition, making the skirt with the same material as the valve can omit certain necessary processes such as verifying the biological nature of the material, as the material of the valve is already well known, thereby facilitating the promotion and implementation of the stent apparatus.

Preferably, during the operation of the stent, a side wall of the stent faces a branch blood vessel, and the skirt in the stacked configuration is provided to avoid the branch vessel in an axial position.

For example, there are multiple branch vessels at the aortic arch, so the peripheral leakage occluder having a stacked skirt should be provided to avoid the branch vessels.

Preferably, during the operation of the stent, the skirt in the stacked configuration avoids a channel formed in the stent in an axial position for allowing blood to smoothly flow therethrough.

Similarly, even if there is no clear branch vessel, some portion of the stent must be hollow to allow blood to smoothly flow therethrough; in this condition, the peripheral leakage occluder with the stacked skirt should be provided to avoid the hollow channel. Taking the aortic valve stent as an example, the peripheral leakage occluder should be located upstream of the blood flow relative to the valve. Therefore, the skirt is generally arranged closer to the blood inflow end of the stent than the valve. The axial position of the skirt in the unfolded configuration affects the position of the peripheral leakage occluder which is formed by axially folding the skirt.

Preferably, a first skirt and a second skirt are arranged one above the other in the axial direction, and the first skirt in the stacked configuration forms a first peripheral leakage occluder and the second skirt in the stacked configuration forms a second peripheral leakage occluder.

The arrangement of two peripheral leakage occluders not only solves the problem of the limited axial fold of a single skirt, but also provides a better sealing effect on the peripheral leakage in practice.

However, if there is provided too many skirts, the problem of insufficient radial expansion for an individual peripheral leakage occluder will arise.

Optionally, each of the two skirts is transformed independently from the unfolded configuration into the stacked configuration using the same or different driving techniques.

There are various driving techniques and different influence factors for the folding of the skirt. Different skirts are not strictly required to be released and stacked using the same technique, but may be driven to fold in different cooperation modes according to the respective positions of the skirts.

Preferably, the two peripheral leakage occluders are spaced from each other.

The skirts being folded are generally moved towards their respective fixing bands. Therefore, if two fixing bands are too close to each other, the first and second peripheral leakage occluders formed by the two skirts may get too close to each other. In contrast, if the fixing bands of the two skirts are spaced from each other, for example, each of the two skirts is provided with a fixing band at the respective top edge, then the resulting first and second peripheral leakage occluders will move towards the top edges of the respective skirts, with intervals formed therebetween.

The arrangement of the two spaced peripheral leakage occluders can achieve double sealing. If there is only a single occluder, the sealing effect would be affected once a defect occurs.

Preferably, in the unfolded configuration of the skirt, the stent has flared driving structures at positions corresponding to both of the skirts.

In order to facilitate the smooth transformation of the skirts into the stacking configurations, the flared driving structures may be provided at the positions of the stent corresponding to both of the skirts. The flared driving structures corresponding to the two skirts may taper in the same or different ways. The flared driving structures corresponding to the two skirts may extend continuously to each other or be connected to each other. Alternatively, the flared driving structures may be spaced from each other, that is, the section of the stent between the two flared driving structures is a straight section.

Preferably, the first peripheral leakage occluder is arranged closer to the top of the stent than the second peripheral leakage occluder, and in the unfolded configurations of the two skirts, the axial length of the first skirt which is configured to form the first peripheral leakage occluder has an axial length of 1.5 to 3 times to the axial length of the second skirt which is configured to form the second peripheral leakage occluder.

Since the skirt closer to the top of the stent is longer, after being stacked, the first peripheral leakage occluder has a larger cross section than the second peripheral leakage occluder. That is, after being stacked, the first peripheral leakage occluder at the top has a higher profile and the peripheral leakage occluder at the bottom has a lower profile.

Preferably, in the unfolded configurations of the two skirts, the bottom of the first skirt which is configured to form the first peripheral leakage occluder extends to the top of the second skirt which is configured to form the second peripheral leakage occluder, without overlapping one after the other.

The two skirts in the unfolded configurations are arranged end to end, which not only maximizes the advantages of the sufficient axial lengths thereof, but also avoids an increased radial thickness caused by overlap of the two skirts, thereby ensuring smooth loading of the stent.

Preferably, one side of the skirt is connected to the side wall of the stent, and the other side is connected to the end of the stent.

In other words, one axial side edge of the skirt is exactly connected at the axial edge of the stent, the other axial side of the skirt extends along the outer wall of the stent and is connected at the same.

Preferably, the stent is further provided with a coverage membrane attached to the stent, which extends to the end of the stent where the stent is connected to the skirt.

In other words, both the skirt and the coverage membrane are connected to the same axial side of the stent. The skirt and the coverage membrane may be separately formed or integrally formed as a single piece. The coverage membrane may be either an internal coverage membrane or an external coverage membrane. In the case of the integrally formed structure, the skirt and the coverage membrane are made of the same material. In addition, it is required for the inner coverage membrane inside the stent to extend to the end of the stent, and then turn outwards to form the skirt. In this situation, the integrally formed structure can simplify the cutting process during stitching and maintain the integrity of the stent apparatus.

Preferably, the coverage membrane is attached to the inner wall of the stent, extends to the end (one axial end) of the stent, and then turns outwardly to form the skirt.

Preferably, the stent is further provided with a valve.

Preferably, the skirt is thickened radially in the unfolded or stacked configuration.

An annular protrusion protruding radially may be formed around the outer periphery of the stent by radial thickening, which functions to fill the gap between the stent and the inner wall of the blood vessel, fix the stent, reduce perivalvular leakage and prevent peripheral back flow.

The course of the thickness may follow one or more units; within each unit, the thickness gradually increases from bottom to top, and then decreases gradually. The units may be arranged continuously or discontinuously and the one or more units may have the same or different configurations.

Preferably, the radial thickening may be achieved by a self-folding structure of the skirt.

The folding structure includes at least one of the following techniques: folding circumferentially; folding axially; and folding radially.

The self-folding of the skirt may be achieved by a combination of the above techniques, for example, a spiral structure, which may be regarded as being formed by folding axially and radially. It is obvious that the above techniques are not exhaustive. In practice, there may also be more complicated or irregular folding structures, however, in any event, at least a radial expansion is formed.

In order to maintain the shape of the folding structure, as preferred, a pulling string is provided through the folded structure, which will be further described below.

As further preferred, the folding structure is formed by: the skirt simultaneously extending upwardly from the end of

the stent (one axial end where the skirt is connected to the inner coverage membrane) and folding radially, to the top edge of the peripheral leakage occluder, and then turning outwardly and extending downwardly to the bottom edge of the peripheral leakage occluder.

As further preferred, the folding structure is formed by: the skirt simultaneously extending upwardly from the end of the stent and folding radially, to the top edge of the peripheral leakage occluder, and then turning inwardly and attaching with the outer wall of the stent.

Due to the limited thickness of the material, it may be radially thickened by folding itself outwardly or by filling with filler.

Preferably, the skirt itself has a double-layered structure, or a double-layered structure may be formed between the skirt and the inner coverage membrane. The double-layered structure is filled with filler to increase the radial thickness.

Preferably, the filler is made of water-absorbing expansion material. The present invention may adopt a known water-absorbing expansion material. In the prior art, a peripheral leakage occluder made of water-absorbing expansion material has been developed, however, there is still a risk of partial damage and falling-off for such a peripheral leakage occluder.

The stent apparatus is further provided with a pulling string that is configured to drive the skirt to transform into the stacked configuration. The pulling string operates in cooperation with the radial deformation of the stent during release.

As a driving mechanism that drives the skirt to get into the stacked configuration, the pulling string operates in cooperation with the radial deformation of the stent during release.

In addition to causing the skirt to be stacked using the existing characteristics of the stent and the skirt, a driving mechanism may also be provided. During the release of the stent, the skirt of the present disclosure is transformed from the unfolded configuration which is relatively flat to the stacked configuration in the axial direction of the stent under the driving mechanism. The skirt being stacked will inevitably be expanded radially, in other words, it will be thickened relative to the corresponding portion of the stent and thus supports or blocks around the periphery of the valve, which is able to effectively reduce the gap between the periphery of the stent and the inner wall of the blood vessel, thereby decreasing the peripheral leakage, and preventing back flow around the periphery of the valve and looseness of the fixed valve stent. Therefore, the current problems of difficult to fix an implanting valve and peripheral leakage may be solved, with the success rate for the operation of an implanting heart valve and the health condition of patients greatly improved.

A pulling string is a preferred driving mechanism.

Optionally, the driving mechanism may be a connecting member that is deformable by changing the environment, thereby pulling the skirt into the stacked configuration. For example, the driving mechanism is a connecting member that maintains an unfolded configuration in a dry environment, and deforms and contracts in water or blood. The connecting member may be a wire or a thread.

Optionally, the driving mechanism may be a preset alloy component such as a nickel-titanium alloy wire which deforms depending on the ambient temperature or external force and pulls the skirt into the stacked configuration.

Optionally, the skirt is provided with a double-layered structure having two layers. The driving mechanism is a water-absorbing expansion material sandwiched between

the two layers of the double-layered structure and deforms after absorbing water to pull the skirt into the stacked configuration.

Due to the pulling string which serves as the driving mechanism in the preferred embodiment of the present disclosure, there are no strict requirements for the engagement between the skirt and the outer periphery of the stent as the skirt can in any event be pulled and stacked by means of the pulling string.

Preferably, the pulling string threads between the skirt and the stent in a circumferential direction.

In order to urge the skirt to transform into the stacked configuration, a pulling string as a preferred driving mechanism is provided to pull the skirt, which extends circumferentially, and threads through or is fixed with, the stent and the skirt.

The driving portions of the pulling string may be a plurality of spaced sections or points, which are fixed with or movably thread through the stent, and may thread through the skirt at corresponding positions while threading through the stent.

The force exerting portions of the pulling string may be a plurality of spaced sections or points, which are fixed with, or movably thread through, the skirt.

During the release of the stent, the radial expansion of the stent is accompanied by changes in the circumferential direction, i.e., the perimeter increases. The pulling string on the stent/skirt operates in cooperation with the radial expanding of the stent. The axial gathering corresponding to the circumferential expanding of the pulling string will drive the skirt to be folded and stacked in the axial direction, and to be further thickened around the outer periphery of the stent, so as to form the annular peripheral leakage occluder.

The length of the pulling string is fixed in both the compressed configuration of the stent before being released and the expanded configuration of the stent after being released. In the expanded configuration of the stent, the pulling string is expanded radially with the expanding of the stent. The axial extension length of the pulling string will be shortened along with the increase of the circumferential extension length of the pulling string, which will simultaneously drive the skirt to be folded axially and transformed into the stacked configuration.

The driving portion and the force exerting portion of the pulling string, as parts of the pulling string, may be segments of the pulling string with certain lengths, or may be certain points. As the stent expands and deforms, the circumferential span of the driving portion increases, and the length of the pulling string in the circumferential direction increases. Accordingly, the force exerting portion interacting with the skirt is pulled to axially move closer thereto, thereby driving the skirt to be folded.

In the compressed configuration of the stent, i.e., in the unfolded configuration of the skirt, the pulling string should be straightened as much as possible or slightly tightened between the two bent points (under the guidance of the stent or the skirt), at least neither being loosened nor extending beyond the axial side of the skirt, in order to provide a timely response to the deformation of the stent being released so as to render the skirt to be pulled axially. Otherwise, the loosened part of the pulling string will delay or even offset the deformation of the stent, which will affect the effect of pulling the skirt. In the expanded configuration of the stent, the length of the pulling string should not be too short to constrain the stent tightly and prevent the stent from expanding.

In the fully expanded configuration of the stent, the pulling string maintains the skirt in the folded and stacked configuration.

During preparation of the stent apparatus, the skirt is maintained in the folded and stacked configuration by the pulling string, while the stent is in the fully expanded configuration. The steps for forming the stent include: a, arranging a prepared skirt around an outer periphery of the stent in a released configuration; b, threading pulling string through the skirt according to a preset course; c, pulling the pulling string to drive the skirt into a stacked configuration; and d, fixing ends of the pulling string.

In the folded and stacked configuration of the skirt, the pulling string extends circumferentially, and preferably, the pulling string is tensioned.

The pulling string that circumferentially extends or is tensioned or tightened does not prevent the stent from expanding.

In the compressed configuration of the stent before being released, the skirt extends axially, and the pulling string extends axially and does not extend beyond the bottom side of the skirt.

Preferably, the pulling string undulates in the axial direction of the stent while extending in the circumferential direction of the stent and thus forms a wave-like configuration.

The pulling string forms an undulating structure while threading along the circumferential direction. The pulling string will be generally subjected to a radial expanding force from the stent being released, and the undulating structure will be expanded to a certain extent, thereby driving the skirt to be axially folded. The pulling string has a larger undulation after the stent is released relative to the stent being unreleased.

Preferably, the pulling string extends circumferentially along the stent for a perimeter.

Preferably, the peaks serve as driving portions which are fixed on the stent, and the valleys serve as force exerting portions which movably thread through the skirt.

The peaks and valleys are relative concepts in this context, which are intended to illustrate the uppermost or lowermost position or the turn-back position of the pulling string in the axial direction. The peaks can be aligned with each other or offset from each other at the same axial level. The same applies to the valleys.

Preferably, the peaks are fixed on the stent, and the valleys movably thread through the skirt. The distance between two adjacent peaks will increase during the release of the stent, while the length of the pulling string which extends between the two adjacent peaks and the valley located between the two adjacent peaks is fixed, thus the valley will be moved towards a line connecting the two adjacent peaks, thereby achieving the axial movement of the skirt and driving the skirt to be generally folded into the stacked configuration.

Preferably, the peaks serve as the first portions which movably thread through the stent, and the valleys serve as the second portions which movably thread through the skirt.

Preferably, the peaks may movably thread through the stent, for example, through gaps of grids of the meshed stent or through holes of the stent or the like. The valleys movably thread through the skirt. The distance between two adjacent peaks will increase during the release of the stent, as the diameter of the stent will increase. However, the overall length of the pulling string is fixed, and therefore the height between the peaks and valleys will reduce, that is, the undulation between the peaks and valleys becomes flatter. As the axial positions of the peaks are limited by the stent,

the valleys move closer to the peaks, thereby achieving the axial movement of the skirt and driving the skirt to be generally folded into the stacked configuration.

Preferably, the peaks serve as the first portions which are fixed with or movably thread through the stent, and the valleys serve as the second portions which are fixed with the skirt.

Similarly, the valleys are pulled by the pulling string during the release of the stent. As the valleys are fixed with the skirt, the skirt can also be pulled.

Different peaks can be connected to the stent using the same or different techniques. Similarly, different valleys can be connected to the stent using the same or different techniques. For example, one of two adjacent peaks is fixed with the stent, and the other movably threads through the stent. In other words, the pulling string may have an undulating structure with similar wave shapes, but the peaks and valleys of the undulating structure may be connected using different techniques.

Preferably, there are at least two pulling strings, and the peaks and valleys of the two pulling strings are arranged in an alternating manner or are spaced from each other.

A plurality of pulling strings may be provided, each of which surrounds the stent for a perimeter. The plurality of pulling strings is arranged one after another in the axial direction. As individual pulling strings have respective undulating structures, the plurality of pulling strings may be arranged in an alternating manner along the axial direction.

Appropriate alternating manner functions to control the stacking of the skirt, thereby improving the sealing effect.

Preferably, within one wave of the undulating structure, the axial height of the wave is greater than the circumferential length of the wave, which can improve the pulling performance and obtain a greater axial displacement under a certain radial deformation of the stent.

Preferably, the driving portions are only connected to the skirt, and at least a part of the driving portions is fixed with or threads through the skirt. The driving portions at least comprise two threading ends interacting with the skirt, with the circumferential span therebetween changed after the stent is released relative to the stent being unreleased.

One driving mechanism is configured as the pulling string connected between the stent and the skirt which is fixed to the stent or at least threads through the stent to form a bent course. The present disclosure also provides another pulling string which only threads through the skirt and is located around the outer periphery of the stent, and is neither fixed with the stent, nor bent by directly utilizing any structural gap of the stent.

The pulling string also forms an undulating structure while threading through the skirt along the circumferential direction. The overall pulling string will be subjected to a radial supporting and expanding force of the stent being released, and its undulating structure will be changed to a certain extent, thereby driving the skirt to be axially folded.

A portion of the pulling string or a single pulling string of a plurality of pulling strings may serve as a single unit for driving a floating section to be folded axially. The principle for one example is the deformation mechanism of a triangle; that is, in the case that the overall length of two sides of the triangle are fixed, the angle between the two sides with fixed length will increase when the length of the third side is increased, and the vertex corresponding to the two sides will get closer to the third side.

The pulling string itself may be considered as the two sides with fixed length, with a bent portion therebetween which may be considered as the intersection point of the two

sides. During the release of the stent, the perimeter of the skirt will increase, which means that the length of the third side of the triangle increases, and the intersection point therefore will get closer to the third side.

If more bent portions are provided, the single unit may be developed as a quadrangle or a polygon instead of triangle, in which each side may be a straight or curved side when tensioned. The bent portions may be provided by the stent or the skirt, or by additional guide members.

Preferably, the pulling string which serves to work on the floating section includes one or more pulling units. Each pulling unit includes at least two threading ends interacting with the skirt, and at least one force exerting portion is formed by at least a part of the pulling unit between the two threading ends and connected to the skirt. The pulling string works on the floating section, while it is not directly connected to the stent. Therefore, the force exerting portion is pulled by the relative circumferential displacement of the two threading ends of the pulling unit.

During release, the stent will be generally expanded, thereby pulling the skirt. Before being released, the skirt is folded circumferentially, and it will be unfolded after being released. The two threading ends of the pulling unit acting with the skirt simultaneously move away from each other and pull the force exerting portion to get the skirt to be folded axially.

Taking the deformation mechanism of a triangle as an example, the skirt portion between the two threading ends may be regarded as a third side, the distance of which is changeable, and the force exerting portion may be regarded as a vertex which is axially movable or at least has a movement component in the axial direction. The vertex moves towards the third side during the release of the stent.

The first side of the triangle may be regarded as locating between one of the threading ends and the force exerting portion, and the second side of the triangle may be regarded as locating between the other threading end and the force exerting portion.

Ignoring the elastic deformation of the pulling string itself, the overall length of the first and second sides is substantially fixed. If the force exerting portion is fixed to the skirt, both the length of the first side and the length of the second side are fixed. If the force exerting portion movably threads through the skirt, the respective lengths of the first and second sides may change, while the overall length is fixed.

Although the shape of the triangle may change in various manners or have many deviations, the mechanisms are generally the same, i.e., converting a distance variation between the two points that move relative to each other in the circumferential direction of the skirt during the release of the stent into an axial movement of the third point. This is also the main distinction between the driving mechanism of the present invention and that of the prior art. In the present invention, the floating section is driven to be stacked utilizing the deformation of the pulling string and the stent itself.

Optionally, the force exerting portion is fixed on the skirt or movably threads through the skirt.

The force exerting portion functions to pull the skirt to move axially. One pulling unit may be connected to the skirt via one or more connection points, the one or more connection points may be fixed on or movably thread through the skirt. The skirt is provided with threading holes for the pulling string to pass through.

In the case of movable threading, the force exerting portion is not a fixed portion of the pulling string. The force exerting portion which contacts the skirt during the move-

ment is changeable, that is, the pulling string contacts with the skirt at different positions. Therefore, the force exerting portion is a dynamically changeable portion on the pulling string and referred to as the portion currently contacting the skirt.

Preferably, the at least one force exerting portion comprises a plurality of force exerting portions which are distributed continuously or discontinuously with intervals therebetween; wherein, when the force exerting portions of the pulling string are distributed discontinuously, force is transmitted across the intervals through the skirt.

One or more force exerting portions may be provided in one pulling unit. In the case where the pulling strings between the force exerting portions are discontinuous, the force may be transmitted through the material of the skirt.

The discontinuous pulling strings can be considered as the pulling unit including multiple pulling strings that are not connected directly. In this case, the pulling of the skirt requires the cooperation of multiple pulling strings, and it is impossible to pull the skirt via a single pulling string.

Preferably, the skirt is provided with one or more threading holes, and the at least one force exerting portion movably threads through the one or more the threading holes; and at least one of the one or more threading holes is arranged offset from a line connecting the two threading ends.

During the release of the stent, the two threading ends move away from each other. If all the threading holes are arranged on the line connecting the two threading ends, the relative movement of the two threading ends would not drive the skirt to move, or the axial pull of the skirt is not significant. The extension of the pulling string may be flexibly controlled through the threading holes, which facilitate the cooperation among the multiple pulling units.

Compared with the technique of the force exerting portion being fixed on the skirt and thus pulling the skirt, the technique of the force exerting portion movably threading through the skirt can adjust the position deviation of the skirt resulting from pulling in the circumferential direction, preventing the sealing effect of the peripheral leakage occluder from being weakened due to undesired deformation such as twist.

Preferably, the force exerting portion is located between the two threading ends along an extension direction of the pulling string.

During the release of the stent, the two threading ends move away from each other in the circumferential direction and thus pull the force exerting portion together to make it move axially or at least have a movement component in the axial direction, so as to pull the skirt along two inclined directions.

Preferably, the two threading ends are opposite to each other and located at the same level along the axial direction.

In this case, a maximum relative movement in the circumferential direction can be obtained, otherwise there will be a component in the inclined direction, which will weaken or lower the pulling performance.

Preferably, the pulling string of each pulling unit is configured in a wave-like manner having one or more waves and each wave has a triangle, trapezoid, rectangle or arc shape.

Even within the simplest pulling unit, the force exerting portion and the two threading ends of the pulling unit form an undulated configuration. The pulling unit may include one wave as being a simplest configuration, or more repeated waves as being a complicated configuration. For example, in the case that there is a plurality of threading

holes, the configuration of the pulling unit will be complicated. The common and simple wave shapes are triangle, rectangle, or trapezoid, etc., which facilitate the threading with less interference among different portions of the pulling string.

Since the stent being released expands radially and also shortens axially, both circumferential span and axial length of the pulling unit change during release of the stent. In general, the circumferential span and the axial length change cooperatively.

Preferably, the driving portion extends around the stent for at least a perimeter of the stent, and two ends of the driving portion join together at the force exerting portion.

Preferably, the two ends of the driving portion respectively extend along two sides of a V-shaped course and join together at the force exerting portion. The driving portion extends around the outer periphery of the stent. During the deformation of the stent, the driving portion is expanded and then the vertex of the V-shaped course is pulled to move axially.

Preferably, the driving portion threads through the stent, or is only located around the outer periphery of the stent.

In order to define the extending course of the pulling string, the pulling string may movably thread through the stent or the skirt at the positions where a position limit is required, in particular, to form the V-shaped configuration.

For example, in the case where the skirt has a large profile in the preset configuration, the string is not tensioned and the portion of the skirt circumferentially enclosed by the pulling string is not attached to the stent, so that the pulling string would not be pulled when the stent expands.

Preferably, the pulling string is only provided on and threads through the skirt, and the pulling string undulates in the axial direction of the stent while extending in the circumferential direction of the stent and thus forms a wave-like configuration, and the wave shape of the pulling string is changed when the pulling string is driven by the deformation of the stent during release so as to pull the skirt into the stacked configuration.

Although the pulling string is not directly connected to the stent, it still extends around the outer periphery of the stent. When the stent is radially expanded, an enclosed area of the pulling string will be enlarged, resulting in a changed wave shape. The waves may have various shapes, and the shapes of the waves may be the same or different.

Preferably, the waves of the pulling string are distributed periodically, and the shape of the one or more waves within each cycle may be one or any combination of a triangle, a rectangle and a trapezoid.

Preferably, the skirt is provided with a first set of threading holes and a second set of threading holes, with each set of threading holes comprising a plurality of threading holes arranged in a circumferential direction, the two sets of threading holes are arranged one above the other in the axial direction, and the pulling string alternatively threads through the first set of threading holes and the second set of threading holes and forms the wave-like configuration.

Preferably, the pulling string alternatively threads into and out of the surface of the skirt.

Preferably, the two sets of threading holes have the same number of threading holes and the threading holes of the first set are arranged offset from the threading holes of the second set.

The present disclosure also provides a heart valve comprising a cylindrical meshed stent and a valve provided in

the stent, wherein the stent is the stent apparatus for preventing peripheral leakage according to the present disclosure.

The valve in the stent apparatus can form a one-way blood channel, and the valve in the stent and the skirt located around the outer periphery of the stent can be made of the same or different materials.

The present disclosure also provides a processing method for the stent apparatus for preventing peripheral leakage, including the steps of:

- a. arranging a prepared skirt around an outer periphery of the stent in an expanded configuration;
- b. threading a pulling string through the skirt according to a preset course;
- c. pulling the pulling string to drive the skirt to transform into the stacked configuration; and
- d. fixing ends of the pulling string.

The length of the pulling string is related to the size of the skirt corresponding to the expanded stent, the perimeter of the expanded stent, and the size and number of peripheral leakage occluders. Before the stent is loaded and compressed, the skirt has been stitched on the stent. Since the stent is generally in an expanded configuration during stitching, the configuration of the skirt after being stitched and before being loaded is basically the same as that of the skirt after the stent is released in the human body, i.e., the stacked configuration of the skirt after the stent is released. Therefore, it may be regarded that the process of stitching the skirt on the stent is a process to predefine the configuration of the skirt. In order to reduce the radial dimension during loading, the predefined skirt is axially unfolded. After the stent is released in the human body, the skirt can be restored to the stacked configuration as predefined.

In order to facilitate the threading of the pulling string, preferably, in a step of a, the skirt is flattened around the outer periphery of the stent in the expanded configuration.

Step a further comprises fixing at least a part of the skirt on the stent.

Step a further comprises stitching the skirt as a cylindrical structure which is closed in the circumferential direction before or after the skirt is surrounded around the outer periphery of the stent by prior arts such as stitching or gluing.

With respect to the technique for fixing the ends, preferably, in a step d, the pulling string comprises two ends which are connected with each other. Other than being connected with each other, the ends may also be connected by themselves. The nodes of the ends are just to prevent the pulling string from falling off from the skirt, which is not necessary or strictly limited for driving the skirt to transform into the stacked configuration. Similarly, the step d of fixing ends of the pulling string can also be achieved by tying the ends on the stent.

The present disclosure also provides a folding method for a skirt of a stent apparatus at an implantation site of the stent, wherein the stent apparatus is the stent apparatus with a folded skirt according to the present disclosure, and the skirt comprising:

an unfolded configuration loaded in a sheath before the stent is released, in which the skirt is axially unfolded and surrounds an outer periphery of the stent before being released; and a stacked configuration during or after the release of the stent, in which the skirt is folded and stacked in an axial direction of the stent after being released and forms an annular peripheral leakage occluder;

the stent apparatus is further provided with a pulling string that only threads through the skirt, and the pulling

string operates in cooperation with a radial deformation of the stent during release so as to drive the skirt to transform into the stacked configuration.

The specific structures of the stent apparatus, the skirt and the pulling string involved in the folding method for a skirt may be referred to in the detail disclosures according to the present invention, and will not be repeated here.

The peripheral leakage prevention means provided by the present invention provides an implantable stent that is more suitable with the inner wall of the blood vessels, so that the stent would not be easily migrated and is more stable, with expanded applicable population, lower additional surgical risks, and reduced peripheral leakage, thrombi and other complications. Better hemodynamic performance is provided, the coverage of endothelial cells of the host is enhanced, the probability of occurrence of endocarditis is lowered, and the normal blood supply function of the heart and blood vessels is recovered.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1*a* is a schematic structural view of a traditional aortic stent.

FIG. 1*b* is a schematic structural view of a stent apparatus according to a first embodiment of the present disclosure, showing a stent thereof before being released.

FIG. 1*c* is a schematic structural view of the stent apparatus according to the first embodiment, showing the stent after being released.

FIG. 1*d* is a schematic structural view of a stent apparatus according to an embodiment of the invention

FIG. 1*e* is a schematic structural view of a stent apparatus according to an embodiment of the invention

FIG. 2 is a schematic structural view of a stent apparatus according to a second embodiment of the present disclosure.

FIG. 3*a* is a schematic structural view of a stent apparatus according to a third embodiment of the present disclosure, showing a stent thereof before being released.

FIG. 3*b* is a schematic structural view of the stent apparatus according to the third embodiment, showing the stent thereof after being released.

FIG. 4*a* is a schematic structural view of a stent apparatus according to a fourth embodiment of the present disclosure, showing a stent thereof before being released.

FIG. 4*b* is a schematic structural view of the stent apparatus according to the fourth embodiment, showing the stent thereof after being released.

FIG. 5*a* is a schematic structural view of a stent apparatus according to a fifth embodiment of the present disclosure.

FIG. 5*b* is a schematic structural view of a stent, in which, compared to the stent shown in FIG. 5*a*, both ends thereof are flared.

FIG. 6 is a schematic structural view of a stent apparatus according to a sixth embodiment of the present disclosure.

FIG. 7*a* is a schematic structural view of a stent apparatus according to a seventh embodiment of the present disclosure, showing the stent before being released.

FIG. 7*b* is a schematic structural view of the stent apparatus according to the seventh embodiment, showing the stent after being released.

FIG. 8 is a schematic structural view of a stent apparatus according to an eighth embodiment of the present disclosure.

FIG. 9 is a schematic structural view of a stent apparatus according to a ninth embodiment of the present disclosure.

FIG. 10 is a schematic structural view of a stent apparatus according to a tenth embodiment of the present disclosure.

FIG. 11 is a schematic structural view of a stent apparatus according to an eleventh embodiment of the present disclosure.

FIG. 12 is a schematic structural view of a stent apparatus according to a twelfth embodiment of the present disclosure.

FIG. 13*a* is a schematic structural view of a stent apparatus according to a thirteenth embodiment of the present disclosure, showing the stent before being released.

FIG. 13*b* is a schematic structural view of the stent apparatus according to the thirteenth embodiment, showing the stent after being released.

FIG. 14*a* is a schematic structural view of a stent apparatus according to a fourteenth embodiment of the present disclosure.

FIG. 14*b* is a schematic structural view showing a skirt of the stent apparatus according to the fourteenth embodiment in an unfolded configuration.

FIG. 14*c* is a schematic structural view showing the skirt of the stent apparatus according to the fourteenth embodiment in a stacked configuration.

FIG. 14*d* is a schematic structural view of a stent apparatus which, compared to that of the FIG. 14*b*, shows a pulling string provided.

FIG. 14*e* is a schematic structural view of a stent apparatus which, compared to that of the FIG. 14*c*, shows a pulling string provided.

FIG. 14*f* is a schematic structural view of a stent apparatus with a skirt having a double-layered structure.

FIG. 14*g* is a schematic structural view of a stent apparatus with a skirt having a pleated structure.

FIG. 14*h* is a schematic structural view of a skirt having an alternative double-layered structure.

FIG. 14*i* is a schematic structural view of a skirt in another stacked manner.

FIG. 15*a* is a schematic structural view of a stent apparatus according to a fifteenth embodiment of the present disclosure, showing a stent thereof before being released.

FIG. 15*b* illustrates how a pulling string of the stent apparatus according to the fifteenth embodiment threads through a skirt.

FIG. 15*c* is a schematic structural view of the stent apparatus according to the fifteenth embodiment, showing the stent after being released.

FIG. 16 illustrates how a pulling string of a stent apparatus according to a sixteenth embodiment threads through a skirt.

FIG. 17*a* illustrates how a pulling string of a stent apparatus according to a seventeenth embodiment threads through a skirt.

FIG. 17*b* illustrates how the pulling string of the stent apparatus according to the seventeenth embodiment threads into and out of the skirt.

FIG. 17*c* is a schematic structural view showing the skirt of the stent apparatus according to the seventeenth embodiment in an unfolded configuration.

FIG. 17*d* is a schematic structural view showing the skirt of the stent apparatus according to the seventeenth embodiment in a stacked configuration.

FIG. 18 illustrates how a pulling string of a stent apparatus according to an eighteenth embodiment threads through a skirt.

FIG. 19 illustrates how a pulling string of a stent apparatus according to a nineteenth embodiment threads through a skirt.

FIG. 20*a* is a schematic structural view of a stent apparatus according to a twentieth embodiment of the present disclosure, showing a stent before being released.

21

FIG. 20*b* illustrates how the pulling string of the stent apparatus according to the twentieth embodiment threads through the skirt.

FIG. 20*c* is a schematic structural view of the stent apparatus according to the twentieth embodiment, showing the stent after being released.

FIG. 21 illustrates how the pulling string of the stent apparatus according to the twenty-first embodiment of the present disclosure threads through the skirt.

FIG. 22 illustrates how the pulling string of the stent apparatus according to the twenty-second embodiment of the present disclosure threads through the skirt.

FIG. 23 illustrates how the pulling string of the stent apparatus according to the twenty-third embodiment of the present disclosure threads through the skirt.

FIG. 24 illustrates how the pulling string of the stent apparatus according to the twenty-fourth embodiment of the present disclosure threads through the skirt.

FIG. 25 illustrates how the pulling string of the stent apparatus according to the twenty-fifth embodiment of the present disclosure threads through the skirt.

FIG. 26 illustrates how the pulling string of the stent apparatus according to the twenty-sixth embodiment threads through the skirt.

FIG. 27*a* is a schematic diagram showing the relationship between the circumferential distance variation between a first acting portion and a second acting portion and the axial displacement of a force exerting portion according to a twenty-seventh embodiment of the present disclosure.

FIG. 27*b* is a schematic diagram showing the relationship between the circumferential distance variation between the first acting portion and the second acting portion and the axial displacement of the force exerting portion according to the twenty-seventh embodiment after the shape of a pulling unit is changed.

FIG. 27*c* is a schematic diagram showing the thickness of a peripheral leakage occluder after a skirt is folded according to the twenty-seventh embodiment.

FIGS. 28*a* to 28*c* are schematic diagrams according to a twenty-eighth embodiment of the present disclosure.

FIG. 29*a* is a schematic diagram of a delivery system according to a twenty-ninth embodiment of the present disclosure.

FIG. 29*b* is a schematic view according to the twenty-ninth embodiment, in which a stent with a skirt is in a loaded configuration.

FIG. 29*c* is a schematic view according to the twenty-ninth, in which the stent with the skirt is in an intermediate state during release.

FIG. 29*d* is a schematic view according to the twenty-ninth, in which the stent with the skirt is in a released configuration.

FIG. 29*e* is a schematic view according to the twenty-ninth embodiment, showing the delivery system entering into the aortic valve.

FIG. 29*f* is a schematic view according to the twenty-ninth embodiment, in which the stent in the delivery system is being released to an intermediate state at the aortic valve.

FIG. 29*g* is a schematic view according to the twenty-ninth embodiment, in which the stent in the delivery system is fully released at the aortic valve.

## DESCRIPTION OF THE EMBODIMENTS

In order to make the technical solutions of the embodiments more apparent and complete, the present disclosure will be further described in detail below with reference to

22

accompanying drawings and embodiments. It should be understood that the embodiments described are illustrated as a part of the embodiments according to the present disclosure, but not exhaustive. Any modifications obtained by those skilled in the art based on the descriptions of the embodiments of the present disclosure without inventive efforts are also within the scope of the present disclosure.

In order to clearly describe and illustrate the embodiments of the present application, one or more figures may be referred to, while the additional details or illustrations for describing the figures should not be regarded as any limitations to any one of the present disclosure, the embodiments described hereinafter, and the preferred embodiments of the present application.

In the stent apparatus for preventing peripheral leakage according to the present invention, the stent may be any known stent in the art. After entering into the body, the distal axial end of the stent is released first, and then a proximal end is to be released later. During release of the stent, any axial end thereof may serve as the distal end, with the other end thereof as the proximal end, which depends on physiological structures of different lesion sites in the human body and operating methods of implantation surgeries. In FIG. 1*a*, an aortic stent including a stent 1 is taken as an example. The stent 1 is made of material such as nickel-titanium alloy. A fixing ear 1*b* is provided at the top of the stent (referring to the orientations shown in the figures) for connecting with a delivery system. Depending on the applications and requirements of the stent, a valve 1*a* or an inner coverage membrane 1*c* may be provided in the stent. The peripheral leakage referred in the present invention is not strictly limited to the aortic valve, but also may occur in other positions in the human body with similar physiological structures.

Unless otherwise specified, in the figures of the following embodiments: solid triangular boxes illustrate that the designated portions of a pulling string are fixed to the stent. If the area of the stent corresponding to the pulling string is also surrounded by the skirt, the pulling string may or may not thread through the area of the skirt as required. Hollow triangular boxes illustrate that the designated portions of the pulling string movably thread through the stent. If the area of the stent corresponding to the pulling string is surrounded by the skirt, the pulling string may or may not thread through the area of the skirt as required; solid rectangular boxes illustrate that the designated portions of a pulling string are fixed to the skirt and extend around the outer periphery of the stent without threading through the interior of the stent. Hollow rectangular boxes illustrate that the designated portions of the pulling string movably thread through the skirt and extend around the outer periphery of the stent without threading through the interior of the stent.

## First Embodiment

Referring to FIGS. 1*b* and 1*c*, the stent apparatus according to a first embodiment of the present disclosure includes a stent 1 with a flexible skirt 2 provided on the outer periphery. Before being released, i.e., before being radially expanded, the stent is in a radial compressed configuration. Before implantation, the stent is loaded into a delivery system and generally retains said compressed configuration under the constraint of a sheath.

Before the stent 1 is released, the skirt 2 is in an unfolded configuration in an axial direction, which is axially unfolded and surrounds the outer periphery of the stent 1. The axial unfolding of the skirt is caused by an inner wall of the sheath

which axially drags the skirt during the loading process. In order to improve the compliance of the skirt, a skirt having an outer diameter as small as possible should be used. Further, the skirt is required to be unfolded as much as possible to avoid being folded or overlapped.

During the release of the stent, the expanded stent is gradually constrained by at least a portion of the skirt, and the skirt is axially pulled to form a peripheral leakage occluder upon further release of the stent.

Valves may be provided in the stent, depending on the practical application; for example, the resulting stent apparatus may serve as a heart valve for preventing perivalvular leakage.

FIG. 1d shows the stent 1 in a configuration during release, in which the bottom of the stent 1 is first released from the sheath of the delivery system and begins to expand radially to form a flared configuration, and the bottom of the skirt 2 (shown in the dashed box) is gradually stacked.

The stent 1 expands radially in the human body after being released from the delivery system. The skirt 2 is in a stacked configuration. The stacking of the skirt 2 is cooperative with the deforming of the stent during release. The skirt 2 is folded and stacked in the axial direction of the released stent to form an annular peripheral leakage occluder. The peripheral leakage occluder may reduce the gap between the outer wall of the stent and the inner wall of the body channel, and prevent regurgitation (i.e., the peripheral leakage). The peripheral leakage occluder formed by the skirt 2 is shown in FIG. 1c.

The skirt 2 is driven by the deformation of the stent 1 being released. In other words, the axial stacking of the skirt 2 is directly caused by the outward expanding of the stent 1. Alternatively, the skirt 2 may be driven by a further combination with other factors, such as the blood flow in the human body, or the shape of the stent 1 or skirt 2. Preferred embodiments are shown below.

Preferably, the skirt 2 is made of flexible material, such as a porcine pericardium, or a bovine pericardium, or other flexible biocompatible materials, which is configured for constraining the outer periphery of the stent after the stent is released. The skirt is substantially in a cylindrical shape, having a diameter smaller than the outer diameter of the portion of the stent in the released state which the skirt surrounds, such that a constraint force is formed by the skirt onto the stent. During the release of the stent, the stent expands radially and outwardly gradually and takes an intermediate configuration with the flared configuration formed at the distal end that is released first, which may guide the flexible skirt to stack in the axial direction.

FIG. 1c shows a two-layer stacked configuration, which is only used for illustration. The practical application may be more complicated, depending on the size and the material of the skirt, which in any event, does not affect the implementation of the invention, i.e., the skirt stacks axially and expands radially to form a peripheral leakage occluder.

In this embodiment, the stent 1 generally has a meshed structure, and one axial side thereof (bottom end in the figures) is provided with a sharp angled structure 1e. The corresponding side of the skirt 2 (bottom end) does not extend axially beyond the tips of the sharp angled structure 1e before the stent 1 is released. In other words, the sharp angled structure 1e is partially exposed to the outside of the skirt 2. When the stent is being released, the tips of the sharp angled structure 1e located at the distal end which is first released will turn outwardly. If the skirt in the unfolded configuration covers the tips of the sharp angled structure 1e,

the tips of the sharp angled structure 1e may snag the inner side of the skirt, which would prevent the skirt from being folded axially.

Actually, the skirt 2 may extend beyond the tips of the sharp angled structure 1e in the axial direction. In this case, a skirt sleeve 1i may be provided and stitched at the bottom end of the stent, as shown in FIG. 1e, which covers the tips of the sharp angled structure to prevent the skirt from being snagged by the tips of the sharp angled structure during the release of the stent, ensuring the stacking of the skirt. Before the stent 1 is released, the skirt 2 in the unfolded configuration has a circumferentially folded structure (shown in the dashed box in FIG. 1b). After the stent 1 is released, the circumferentially folded structure is unfolded due to the radial expanding of the stent. In this embodiment, before the stent 1 is released, the skirt 2 in the unfolded configuration is generally unfolded in a single layer along the axial direction of the stent. The skirt 2 may also have a pleated structure in other embodiments.

In this embodiment, the skirt 2 may generally float around the outer periphery of the stent 1. In other embodiments, the top edge of the skirt may be fixed around the outer periphery of the stent by means of stitching.

#### Second Embodiment

Referring to FIG. 2, in this embodiment, the outer periphery of the stent 1 is provided with flexible skirts. Before the stent 1 is released, the skirts are in unfolded configurations, which are axially unfolded and surround the outer periphery of the stent 1 before release. After the stent 1 is released, the skirts are folded and stacked along the axial direction of the stent 1 after release into stacked configurations and form annular peripheral leakage occluders.

In this embodiment, there are two skirts, i.e. a first skirt 2a and a second skirt 2b, which are arranged one above the other in an axial direction. During the release of the stent, the expanded stent is gradually constrained by at least portions of the skirts, and the skirts are driven to be axially pulled with the further release of the stent. Each skirt is axially pulled and stacked to form a respective peripheral leakage occluder. In order to adapt to the axial movement of the skirts and prevent the skirts from falling off the stent, flexible limiting strings 2c are respectively provided between the stent 1 and the first and second skirts 2a and 2b, and thus security is improved. The limiting string 2c may include a plurality of strips distributed in an axial direction, or a single strip stitched on the periphery of the skirt in a pattern of a rectangular wave.

#### Third Embodiment

Referring to FIGS. 3a and 3b, in this embodiment, the outer periphery of the stent 1 is provided with a flexible skirt 2. Before the stent 1 is released, the skirt 2 is in an unfolded configuration, which is axially unfolded and surrounds the outer periphery of the stent 1 before release. After the stent 1 is released, the skirt 2 is folded and stacked along the axial direction of the released stent 1 into an annular peripheral leakage occluder.

In this embodiment, the stent is a blood vessel stent, which may be used in large vessels such as the aorta. The shape and the application of the stent in this embodiment are different from those disclosed in the previous embodiments, however, the arrangements of the skirt and the functions are similar.

## 25

In this embodiment, the skirt **2** is made of flexible material, and constrains the outer periphery of the stent after the stent is released. During the release, the skirt has not yet constrained the stent, so it is possible for the skirt to adjust its position itself under the blood flow. In order to further limit the position of the skirt, a limiting string may be used in combination with the skirt.

Alternatively, even under the action of the limiting string, the skirt forming the peripheral leakage occluder may also be able to adjust its position itself under the blood flow.

## Fourth Embodiment

Referring to FIGS. **4a** and **4b**, in this embodiment, the outer periphery of the stent **1** is provided with two flexible skirts. Before the stent **1** is released, the skirts are in unfolded configurations, which are axially unfolded and surround the outer periphery of the stent **1** before release. After the stent **1** is released, the skirts are folded and stacked along the axial direction of the released stent into stacked configurations and form annular peripheral leakage occluders.

This embodiment differs from the third embodiment in that the skirts here include a first skirt **2a** and a second skirt **2b** which are arranged one above the other in an axial direction, and each skirt in the stacked configuration forms a respective peripheral leakage occluder.

## Fifth Embodiment

Referring to FIG. **5a**, in which the skirt is omitted, this embodiment differs from the first embodiment in the structure of the stent **1**. In this embodiment, the bottom of the stent **1** is provided with a flared driving structure **1d**, which extends from the middle portion of the stent to the end of the stent (the bottom end). The closer to the bottom end of the stent, the larger the diameter for the flared driving structure **1d**. In this embodiment, the generatrix of the flared driving structure **1d** is substantially straight. The wider side (the bottom end) of the flared driving structure **1d** is released first, and the narrow side is released later. Due to such configuration, the flared structure of the stent may operate in cooperation with the skirt during the release of the stent and guides the skirt to stack axially and stay in the stacked configuration.

As shown in FIG. **5b** in which the skirt or skirts are omitted, and the stent **1** has flared driving structures **1d** at both ends in the axial direction.

## Sixth Embodiment

Referring to FIG. **6**, in which the skirt or skirts are omitted, this embodiment differs from the fifth embodiment in the structure of the flared driving structures **1d**. In this embodiment, the generatrix of the flared driving structure **1d** at the bottom of the stent **1** is substantially curved, and thus has a bottom end turning more outwardly relative to that shown in the fifth embodiment.

## Seventh Embodiment

Referring to FIGS. **7a** and **7b**, this embodiment differs from the first embodiment in that an axial end of the stent **1** has a smooth curved edge, instead of an edge with sharp tips shown in the first embodiment. Before the stent **1** is released, the corresponding side of the skirt **2** extends axially beyond the stent or just extends to the end of the stent.

## 26

In this embodiment, the edge of the distal end of the stent **1** to be released first is formed by a plurality of arc sections **1f** connected one after the other. Since the arc sections **1f** would not pierce or snag the skirt **2**, it is allowable for the skirt **2** to extend axially beyond or exactly to the distal end of the stent to be released first before the stent is released. As a result, a longer skirt may be obtained, which forms a peripheral leakage occluder with a higher profile and a larger volume, thereby improving the sealing effect.

## Eighth Embodiment

Referring to FIG. **8**, in this embodiment, the outer periphery of the stent **1** is provided with a flexible skirt **2**. Before the stent **1** is released, the skirt **2** is in an unfolded configuration, which is axially unfolded and surrounds the outer periphery of the stent **1** before release. After the stent **1** is released, the skirt **2** is folded and stacked along the axial direction of the released stent **1** into a stacked configuration and forms an annular peripheral leakage occluder.

The top edge of the skirt **2** serves as a fixing band **3** which is stitched on the stent with spaced stitching portions **3a** as shown in the figure. At least a part of the skirt **2** remains in a fixed position relative to the stent and is free of the influence of external factors such as blood flow, which functions to control the position of the peripheral leakage occluder.

In this embodiment, a single fixing band **3** is located at the middle portion of the stent, with the remaining skirt there below floating around the outer periphery of the stent **1** before being stacked. Alternatively, it is possible to provide several fixing bands.

The skirt is fixed to the stent only at the fixing band, with the remaining skirt movable relative to the stent. In particular, at least a part of the skirt is movable axially so that it can be folded. In the case of only a single fixing band provided, the remaining skirt floats around the outer periphery of the stent. In the case of several fixing bands provided, the skirt may also be foldable provided that the axial length of the skirt between two adjacent fixing bands is sufficient.

The skirt may be foldable provided that the axial length of the skirt between two fixing bands is sufficient. For example, in the case that the axial length of the corresponding portion of the stent between the two fixing bands is **L1** and the axial length of the skirt between the two fixing bands is **L2**, it is possible for the skirt to be axially stacked provided that **L1** is less than **L2**. The redundant section of the skirt in an unfolded configuration may be overlapped and rested on the outer periphery of the stent, wherein the overlapped sections are folded axially, which will be further described hereinafter.

## Ninth Embodiment

Referring to FIG. **9**, this embodiment differs from the eighth embodiment in that the fixing band **3** here is located at the bottom of the stent, and the remaining skirt above the fixing band floats around the outer periphery of the stent **1** before being stacked.

## Tenth Embodiment

Referring to FIG. **10**, the stent in this embodiment has a meshed structure with a plurality of grids. This embodiment differs from the eighth embodiment in that the fixing band **3** here is stitched on the meshed stent by a continuous stitch line **3b**. Corresponding to the grids of the meshed stent, the

27

stitch line **3b** undulates in the axial direction while extending in the circumferential direction, thereby forming a wave-like configuration.

## Eleventh Embodiment

Referring to FIG. 11, in this embodiment, the outer periphery of the stent **1** is provided with a flexible skirt **2**. Before the stent **1** is released, the skirt **2** is in an unfolded configuration, which is axially unfolded and surrounds the outer periphery of the stent **1** before release. After the stent **1** is released, the skirt **2** is folded and stacked along the axial direction of the stent **1** after release into a stacked configuration and forms an annular peripheral leakage occluder.

The stent is an aortic valve stent, and valves are provided in the stent. In operation, the stent is implanted at the lesion site at the aortic valve of a human heart. Since there is a coronary sinus distributed around the aortic valve annulus, depending on the physiological structure of the lesion site, after the stent is released, a hollow area **1g** should be free from coverage by the skirt **2**, otherwise the skirt **2** would block the blood flow into the coronary sinus. Thus, the skirt should be provided at an axial position which avoids the channel (the hollow area **1g**) formed on the stent for blood flow.

The skirt may be made of the same material as the valve, such as animal pericardium or other biocompatible flexible materials.

## Twelfth Embodiment

Referring to FIG. 12, in this embodiment, the outer periphery of the stent **1** is provided with a flexible skirt. Before the stent **1** is released, the skirt is in an unfolded configuration, which is axially unfolded and surrounds the outer periphery of the stent **1** before release. After the stent **1** is released, the skirt **2** is folded and stacked along the axial direction of the stent **1** into a stacked configuration after release and forms an annular peripheral leakage occluder.

This stent **1** is generally configured to be applied to the aortic arch. Due to the physiological structure of the aortic arch, the side wall of the stent would face the branch blood vessels **1h** after the stent is released, which, should be free from coverage by the skirt **2**, otherwise, the blood flow would be blocked. Therefore, the stacked skirt should be provided to avoid the branch blood vessels **1h** in the axial position.

## Thirteenth Embodiment

Referring to FIGS. 13a and 13b, in this embodiment, the outer periphery of the stent **1** is provided with flexible skirts. Before the stent **1** is released, the skirts are in unfolded configurations, which are axially unfolded and surrounds the outer periphery of the stent **1** before release. After the stent **1** is released, the skirts are folded and stacked along the axial direction of the stent after release into stacked configurations and form annular peripheral leakage occluders. In this embodiment, there are two skirts, i.e., a first skirt **2d** and a second skirt **2e**. Each of the first and second skirts **2d** and **2e** in the stacked configuration forms a respective peripheral leakage occluder.

The top edges of the first and second skirts **2d** and **2e** are connected to the stent at two fixing bands **3d** and **3e**, respectively, by means of spaced stitching portions or continuous stitch lines. The ends of the first and second skirts **2d** and **2e** opposite to the top edges are floating edges.

28

The first skirt **2d** in the stacked condition is configured to form a first peripheral leakage occluder, and the second skirt **2e** in the stacked condition is configured to form a second peripheral leakage occluder. The two peripheral leakage occluders are separated. The first peripheral leakage occluder is arranged closer to the top of the stent than the second peripheral leakage occluder. In the unfolded configurations, the first skirt **2d** has an axial length of 1.5 to 3 times to the axial length of the second skirt **2e**. After being stacked, the first peripheral leakage occluder generally has a larger cross section than the second peripheral leakage occluder. That is, after being stacked, the first peripheral leakage occluder at the top has a higher profile and the peripheral leakage occluder at the bottom has a lower profile. In the unfolded configurations, the bottom edge of the first skirt **2d** extends to the top edge of the second skirt **2e**, without overlapping one after the other. That is, the first and second skirts are arranged end to end, which not only maximizes the advantages of the sufficient axial lengths thereof, but also avoids an increased radial thickness caused by overlap of the first and second skirts so as to ensure smooth loading of the stent, i.e., compression of the stent into the delivery system.

## Fourteenth Embodiment

Referring to FIGS. 14a to 14c, in this embodiment, the outer periphery of the stent **1** is provided with a flexible skirt. Before the stent **1** is released, the skirt is in unfolded configuration, which is axially unfolded and surrounds the outer periphery of the stent **1** before release. After the stent **1** is released, the skirt is folded and stacked along the axial direction of the stent **1** after release into a stacked configuration and forms an annular peripheral leakage occluder.

As shown in FIG. 14a, in this embodiment, valves **1a** and an inner coverage membrane **1c** are provided in the stent **1**. The top edge of the skirt **2** is connected to the stent at a first fixing band **3f**, and the bottom edge of the skirt **2** is connected to the bottom edge of the stent at a second fixing band **3g**, wherein the first and second fixing bands **3f** and **3g** may be stitched by means of spaced stitching portions or continuous stitch lines, respectively.

The inner coverage membrane **1c** inside the stent extends to the bottom end of the stent, and the bottom edge of the skirt **2** outside the stent also extends to the bottom end of the stent. The inner coverage membrane **1c** and the skirt **2** may be separately formed or integrally formed as a single piece. In this embodiment, it is preferred to form them as a single piece, in which case the inner coverage membrane inside the stent first extends to the end of the stent, and then turns outwards to form the skirt, which may simplify the cutting process during stitching and maintain the integrity of the stent apparatus.

As shown in FIG. 14b, the inner coverage membrane **1c** is integrally formed with the skirt **2** as a single piece. This embodiment differs from the embodiment shown in FIG. 14a in that only a single fixing band **3f** is provided. The skirt **2** first extends upwardly from the position where the skirt **2** is connected with the inner cover **1c**, i.e. the bottom edge of the stent **1**, to the axially highest end of the skirt **2**, i.e. the top of the skirt. The top edge of the skirt **2** is connected to the stent at the fixing band **3f**. The skirt **2** then turns downwards from the highest end and forms an evaginated floating section **2f**. The floating section **2f** is axially extended before the stent **1** is released. After the stent **1** is released, the floating section **2f** is stacked under elastic effect or blood flow. In addition, the floating section **2f** may also be pulled

and stacked in combination with the pulling string of the present invention to form an annular protrusion protruding radially to serve as a peripheral leakage occluder.

The configuration in FIG. 14c may also be shaped by stitching in advance. The unfolded configuration of the skirt in the axial direction is obtained only by compressing radially, with the folded configuration still retained. After the stent is released, the floating section 2f in the human body will expand further through the influence of blood flow or the like.

Referring to FIGS. 14d and 14e, the transition of the skirt 2 from the unfolded configuration to the stacked configuration will be described in a further development in combination with the arrangement of the skirts shown in FIGS. 14a to 14c.

A pulling string 4 is provided on the floating section 2f of the skirt. The pulling string 4 generally threads through the floating section 2f in the circumferential direction. The pulling string 4 undulates in the axial direction while extending along the circumferential direction of the stent, forming a wave-like configuration with peaks and valleys. In the unfolded configuration, the peaks are at the same level in the axial position, and the valleys are at the same level in the axial position. Alternatively, the peaks (or the valleys) may be offset from each other.

In order to facilitate the threading of the pulling string, a set of first threading holes is provided on the skirt corresponding to the peaks, and a set of second threading holes is provided corresponding to the valleys. The pulling string alternately threads the first threading hole and the second threading hole and forms a wave-like configuration. The pulling string alternately threads into and out of the surfaces of the skirt.

Two adjacent peaks serve as two threading ends operating in cooperation with the skirt. The circumferential span between the two threading ends is changed after the release of the stent relative to the stent being unreleased. During the release of the stent, driven by the deformed stent, the peaks move away from each other in the circumferential direction and thus drive the valleys to lift upwardly, thereby axially stacking the floating section 2f.

The peaks and valleys are relative concepts. Actually, either one can be designated as the peak, and the other one can be designated as the valley. During the release of the stent, driven by the deformed stent, the valleys also move away from each other in the circumferential direction and thus drive the peaks to move axially. Therefore, the movements of the peaks and valleys are relative to each other. In any case, the intention is to drive the peaks and valleys to move axially towards each other.

Referring to FIG. 14f, in a further development, the skirt 2 has a double-layered structure which is filled with a water-absorbing expansion material. After being released in the human body, the water-absorbing expansion material absorbs water and expands radially. Due to the coverage of the skirt made of a membrane material, the risk of the water-absorbing expansion material falling off can be avoided.

Referring to FIG. 14g, in a further development, the skirt 2 may have folded sections in a circumferential direction which overlap one after the other in a radial direction to cooperatively form a radial protrusion.

Referring to FIG. 14h, in a further development, an interlayer is provided between the skirt 2 and the inner coverage membrane 1c, which may be formed by folding a part of the skirt 2. Preferably, the inner coverage membrane 1c extends upwardly from the bottom edge of the stent. The

top of the interlayer is fixed on the stent. The skirt turns downwards from the top of the interlayer and may be configured as a floating section that floats outside the interlayer. The skirt may be fixed on the interlayer or at a bottom of the interlayer, or may be fixed on the inner coverage membrane 1c. The floating section may be pulled and stacked using the technique shown in FIG. 14e to form an annular protrusion protruding radially to serve as a peripheral leakage occluder.

Referring to FIG. 14i, in a further development, the skirt 2 extends upwardly from the position where the skirt 2 is connected with the inner coverage membrane 1c, that is, from the bottom edge of the stent 1. The entire upwardly extending portion of the skirt 2 is configured as a floating section 2f, with the end of the floating section 2f distant from the bottom edge being a floating edge. The floating section 2f is axially unfolded before the stent 1 is released, and may be pulled and stacked using the technique shown in FIG. 14e to form an annular protrusion protruding radially to serve as a peripheral leakage occluder. The difference therebetween is that it is the top edge of the floating section 2f that moves towards the bottom edge here, but the principles are the same.

#### Fifteenth Embodiment

Referring to FIG. 15a and FIG. 15b, in this embodiment, the outer periphery of the stent 1 is provided with a flexible skirt 2. Before the stent 1 is released, the skirt 2 is in an unfolded configuration, which is axially unfolded and surrounds the outer periphery of the stent 1 before release. After the stent 1 is released, the skirt 2 is folded and stacked along the axial direction of the stent 1 after release into a stacked configuration and forms an annular peripheral leakage occluder. Also provided is a pulling string 4 which is configured to drive the skirt 2 to transform into the stacked configuration. The pulling string 4 cooperates with the radial deformation of the stent during release.

The top edge of the skirt 2 is fixed to the outer periphery of the stent 1 by threading the pulling string 4 through the stent and the skirt, and the lower portion of the skirt 2 floats around the outer periphery of the stent 1. The skirt 2 has a circumferential folded structure, which makes it possible for the skirt to conform to the outer periphery of the stent 1 in a flattened manner. After the stent is released, the folded structure is unfolded. During release in the human body, the bottom edge of the skirt 2 is released first, and the top edge of the skirt 2 is released later.

Hollow triangular boxes illustrate that the designated portions of the pulling string movably thread through the stent. In the present embodiment, if the area of the stent corresponding to the pulling string is surrounded by the skirt, the pulling string threads through the corresponding portion of the skirt, thereby axially positioning the skirt on the stent. Hollow rectangular boxes illustrate that the designated portions of the pulling string movably thread through the skirt without threading through the stent.

In this embodiment, the pulling string generally threads between the skirt and the stent in a circumferential direction, which undulates in the axial direction of the stent while extending along the circumferential direction and forms an undulating structure with peaks and valleys. To provide better cooperation, the peaks of the pulling string movably thread through the stent, and the valleys movably thread through the skirt. Within one wave of the undulating structure, the axial length of the wave is greater than the circumferential length of the wave, which can improve the

31

pulling performance and obtain a greater axial displacement under a certain radial deformation of the stent.

Within a periodic portion of the pulling string **4** as shown in the figure, peak **X6**, valley **Y5**, peak **X7**, valley **Y6**, peak **X8** are distributed in the circumferential direction one after the other while undulating in the axial direction. In the unfolded configuration, the peaks are at the same level in the axial position, and the valleys are at the same level in the axial position. Alternatively, the peaks (or the valleys) may also be offset from each other.

During the release of the stent, driven by the deformed stent, the peaks of the pulling string move away from each other in the circumferential direction and thus drive the valleys to lift upwardly. Since the pulling string movably threads through the stent and the skirt, the periodic portions thereof are configured for driving and operating in cooperation with one after another, thereby generally moving the pulling string.

The processing method of the skirt with the pulling string includes the steps of: arranging a prepared skirt around an outer periphery of the stent in an expanded configuration; threading the pulling string through the skirt according to a preset course; pulling the pulling string to drive the skirt to transform into the stacked configuration; and fixing ends of the pulling string.

The length of the pulling string is related to the size of the skirt corresponding to the expanded stent, the perimeter of the expanded stent, and the size and number of peripheral leakage occluders. Before the stent is loaded and compressed, the skirt has been stitched on the stent. Since the stent is generally in an expanded configuration during stitching, the configuration of the skirt after being stitched and before being loaded is basically the same as that of the skirt after the stent is released in the human body, i.e., the stacked configuration of the skirt after the stent is released. Therefore, it may be regarded that the process of stitching the skirt on the stent is a process to predefine the configuration of the skirt. In order to reduce the radial dimension during loading, the predefined skirt is axially unfolded. After the stent is released in the human body, the skirt can be restored to the stacked configuration as predefined.

In order to facilitate the threading of the pulling string, in a step of a, the skirt is flattened around the outer periphery of the stent in the expanded configuration. Optionally, depending on the connection relationship between the pulling string and the stent, at least a part of the skirt may be fixed to the stent.

The skirt is stitched as a cylindrical structure which is closed in the circumferential direction before or after the skirt is surrounded around the outer periphery of the stent.

With respect to the technique for fixing the ends, in a step d, the pulling string comprises two ends which are connected with each other. Other than being connected with each other, the ends may also be connected by themselves. The nodes of the ends are just to prevent the pulling string from falling off from the skirt, which is not necessary or strictly limited for driving the skirt to transform into the stacked configuration. Similarly, the step d of fixing ends of the pulling string can also be achieved by tying the ends on the stent.

#### Sixteenth Embodiment

Referring to FIG. **16**, within a periodic portion of the pulling string **4** according to this embodiment, peak **X6**, valley **Y5**, peak **X7**, valley **Y6**, and peak **X8** are distributed in the circumferential direction one after the other while undulating in the axial direction. Different from the fifteenth

32

embodiment, the peaks here are located at the upper side of the skirt **2**. In other words, the portion of the stent corresponding to the peaks is not covered by the skirt. In this situation, a fixing band may be provided at the top edge of the skirt to further limit the axial position of the top edge of the skirt relative to the stent.

#### Seventeenth Embodiment

Referring to FIG. **17a**, this embodiment differs from the fifteenth embodiment in that two sets of pulling strings **4** are provided here, one above the other in an axial direction, which are configured to pull the corresponding portions of the skirt **2** at different stages during releasing of the stent, respectively. The peaks of the lower pulling string are located higher than the valleys of the upper pulling string. Each pulling string moves together in the circumferential direction to pull the skirt.

Referring to FIG. **17b**, in order to further show the threading of the pulling string through the skirt, the dashed lines in the figure indicate the portions of the pulling string located beneath the skirt, and the solid lines indicate the portions of the pulling string located above the skirt. The pulling string threads into and out of the stent depending on the positional relationship between the pulling string and the skirt (the portion of the pulling string is located beneath or above the skirt). For example, when the pulling string threads through the skirt at peaks **X9** along the direction of arrow **A**, it may be followed by directly threading through the stent and entering into the interior of the stent. However, the pulling string needs to return to the position between the stent and the skirt quickly, and extend between the stent and the skirt to the valleys **Y7** such that the corresponding portion of skirt is capable of floating.

Referring to FIGS. **17c** and **17d**, although the skirt **2** is formed as one single piece, it includes two sections respectively corresponding to the two pulling strings. Skirt sections **2h** and **2i** are axially folded at the outer periphery of the stent **1** to float. The skirt section **2i**, after being fixed with the stent **1**, extends downwardly (i.e. towards the end of the stent) to form the skirt section **2j** which independently serves as a floating section and the free end thereof is a floating edge.

The connection of the skirt sections **2h** and **2i** is located below the top edge of skirt section **2j**, so that the peaks and valleys of the two pulling strings may be distributed in an alternating manner. In the stacked configuration, the skirt sections **2h** and **2i** are stacked subject to the pulling of the upper pulling string without affecting the skirt section **2j**, and the skirt section **2j** is stacked independently subject to the pulling of the lower pulling string.

#### Eighteenth Embodiment

Referring to FIG. **18**, this embodiment differs from the fifteenth embodiment in the wave shape of the undulating structure of the pulling string **4**. In this embodiment, the pulling string follows a course having a wave shape with sharp peaks and flat valleys. The portions of the stent where the pulling string movably threads through are surrounded by the skirt **2**.

#### Nineteenth Embodiment

Referring to FIG. **19**, this embodiment differs from the seventeenth embodiment in the wave shape of the undulating structure of the pulling string **4**. The wave shapes of the

two pulling strings are different. The upper pulling string follows the course having a wave shape with flat peaks and flat valleys, and the lower pulling string follows a course having a wave shape with flat peaks and sharp valleys. The portions of the stent where the pulling string movably threads through are surrounded by the skirt 2.

#### Twentieth Embodiment

Referring to FIGS. 20a to 20c, in this embodiment, the outer periphery of the stent 1 is provided with a flexible skirt 2. Before the stent 1 is released, the skirt 2 is in an unfolded configuration, which is axially unfolded and surrounds the outer periphery of the stent 1 before release. Preferably, the perimeter of the skirt is equal to or slightly greater than the perimeter of a corresponding portion of the stent so that the skirt conforms around the corresponding portion of the stent. Also provided on the skirt is a pulling string 4 that is configured to drive the skirt into a stacked configuration. The pulling string 4 cooperates with the radial deformation of the stent 1 during release. When the stent is being released in the human body, the bottom edge of the skirt 2 is released first, and then the top edge of the skirt 2 is released later. After the stent 1 is released, the skirt 2 is in the stacked configuration, which is folded and stacked along the axial direction of the stent 1 after release and forms an annular peripheral leakage occluder.

The top edge of the skirt 2 serves as a fixing band 3, which may be stitched on the stent using the same stitching technique as shown in FIG. 8 with spaced stitching portions. At least a part of the skirt 2 remains in a fixed position relative to the stent and is free of the influence of external factors such as blood flow, which functions to control the position of the peripheral leakage occluder. In this embodiment, a single fixing band 3 is provided at the middle portion of the stent, and the portion of the skirt below the fixing band 3 floats around the outer periphery of the stent 1 before being stacked.

Alternatively, the fixing band may be fixed on the stent using the same stitching technique as shown in the tenth embodiment. The stitch line on the fixing band 3 may undulate in the axial direction while extending in the circumferential direction. In other words, the corresponding portion of the stent has a meshed structure with a plurality of grids, and the stitch line extends along the edges of the grids and forms a wave-like configuration.

The hollow boxes in the figures illustrate that the portion of the pulling string here threads through the skirt without threading through the stent.

In this embodiment, the pulling string generally threads through the skirt in a circumferential direction, which undulates in the axial direction of the stent while extending in the circumferential direction of the stent, thereby forming a wave-like configuration with peaks and valleys.

Within a periodic portion of the pulling string 4, peak X6, valley Y5, peak X7, valley Y6, peak X8 are distributed in the circumferential direction one after the other while undulating in the axial direction. In the unfolded configuration, the peaks are at the same level in the axial position, and the valleys are at the same level in the axial position. Alternatively, the peaks (or the valleys) may also be offset from each other.

In order to facilitate the threading of the pulling string, a set of first threading holes is provided on the skirt corresponding to the peaks, and a set of second threading holes is provided corresponding to the valleys. The pulling string alternatively threads the first threading hole and the second

threading hole and forms the wave-like configuration. The pulling string alternatively threads into and out of the surfaces of the skirt.

Two adjacent peaks may serve as the driving portion of the pulling string, i.e., the two threading ends interacting with the skirt. The circumferential span between two threading ends such as the above-mentioned peaks X6 and X8 is changed after the stent is released relative to the stent being unreleased.

During the release of the stent, the stent drives the pulling string on the skirt. Driven by the deformed stent, the peaks of the pulling string move away from each other in the circumferential direction and thus drive the valleys to lift upwardly. Since the pulling string movably threads through the skirt, the periodic portions thereof are configured for driving and operating in cooperation with one another, thereby generally moving the pulling string. The peaks and valleys are relative concepts. Actually, either one may be designated as the peak, and the other one can be designated as the valley. During the release of the stent, driven by the deformed stent, the valleys move away from each other in the circumferential direction and thus drive the peaks to move axially. Therefore, the movements of the peaks and valleys are relative to each other. In any case, the intention is to drive the peaks and valleys to move axially towards each other.

During manufacturing, the top edge of the skirt is first fixed on the preformed stent, the pulling string is circumferentially provided on the skirt, then the pulling string is tensioned to fold the skirt and finally the two ends of the pulling string are connected.

The length of the pulling string is related to the size of the skirt corresponding to the expanded stent, the perimeter of the expanded stent, and the size and number of peripheral leakage occluders. Before the stent is loaded and compressed, the skirt has been stitched on the stent. Since the stent is generally in a released configuration during stitching, the configuration of the skirt after being stitched and before being loaded is basically the same as that of the skirt after the stent is released in the human body, i.e., the stacked configuration of the skirt after the stent is released. Therefore, it may be regarded that the process of stitching the skirt on the stent is a process to predefine the configuration of the skirt. In order to reduce the radial dimension during loading, the predefined skirt is axially unfolded. After the stent is released in the human body, the skirt can be restored to the stacked configuration as predefined.

During stitching, the stent may take a full or partial compressed configuration, and thus the configuration of the skirt during stitching in the present disclosure is not limited.

#### Twenty-First Embodiment

Referring to FIG. 21, this embodiment differs from the twentieth embodiment in that two sets of pulling strings 4 are provided here, one above the other in an axial direction, which are configured to pull the corresponding portions of the skirt 2 at different stages during releasing of the stent, respectively. The peaks of the lower pulling string are located higher than the valleys of the upper pulling string. Each pulling string moves together in the circumferential direction to pull the skirt.

In order to further show the threading of the pulling string through the skirt, the dashed lines in FIG. 21 indicate the portions of the pulling string located beneath the skirt, and the solid lines indicate the portions of the pulling string located above the skirt. Since the pulling strings are not fixed

35

on or thread through the stent, and thus other than the fixing band, the remaining portions of the skirt may serve as floating sections, the two sets of pulling strings may interact with each other via force transmitted by the skirt.

Twenty-Second Embodiment

Referring to FIG. 22, this embodiment differs from the twentieth embodiment in the wave shape of the undulation of the pulling string 4. In this embodiment, the pulling string follows a course having a wave shape with sharp peaks and flat valleys.

Twenty-Third Embodiment

Referring to FIG. 23, this embodiment differs from the twentieth embodiment in the wave shape of the undulation of the pulling string 4. In this embodiment, the pulling string follows a course having a wave shape with flat peaks and flat valleys.

Twenty-Fourth Embodiment

Referring to FIG. 24, this embodiment differs from the twentieth embodiment in the wave shape of the undulation of the pulling string 4. In this embodiment, the pulling string follows a course having a wave shape with flat peaks and sharp valleys.

Twenty-Fifth Embodiment

Referring to FIG. 25, this embodiment differs from the twenty-second embodiment in that portions of the pulling string 4 corresponding to the peaks here are fixed on the skirt 2.

Twenty-Sixth Embodiment

Referring to FIG. 26, this embodiment differs from the twentieth embodiment in that portions of the pulling string 4 corresponding to the valleys here are fixed on the skirt 2.

Twenty-Seventh Embodiment

As shown in FIGS. 27a and 27b, in this embodiment, a single pulling unit is taken as an example for illustration. Assuming that the length of the pulling string is I, the distance between the first acting portion X1 and the second acting portion X2 before being pulled is a, and the distance between the force exerting portion Y1 and a line connecting the first acting portion X1 and the second acting portion X2 before being pulled is h.

Before being pulled, the distance between the first acting portion X1 and the force exerting portion Y1 is b.

Before being pulled, the distance between the second acting portion X2 and the force exerting portion Y1 is b.

Before being pulled, the overall length of the pulling string of the pulling unit in FIG. 45a is 2b, where 2b=I.

After being pulled, the distance between the first acting portion X1 and the second acting portion X2 is A, and the distance between the force exerting portion Y1 and a line connecting the first acting portion X1 and the second acting portion X2 is H.

After being pulled, the distance between the first acting portion X1 and the force exerting portion Y1 is B.

After being pulled, the distance between the second acting portion X2 and the force exerting portion Y1 is B.

36

After being pulled, the overall length of the pulling string of the pulling unit in FIG. 45b is 2B, where 2B=I.

After being pulled, the circumferential distance variation of the pulling wire is Δa, where Δa=A-a. The axial distance variation of the force exerting portion Y1 before and after being pulled is:

$$\begin{aligned} \Delta h &= h - H = \sqrt{b^2 - \left(\frac{a}{2}\right)^2} - \sqrt{B^2 - \left(\frac{A}{2}\right)^2} \\ &= \sqrt{\left(\frac{I}{2}\right)^2 - \left(\frac{a}{2}\right)^2} - \sqrt{\left(\frac{I}{2}\right)^2 - \left(\frac{A}{2}\right)^2} \\ &= \frac{\sqrt{I^2 - a^2} - \sqrt{I^2 - A^2}}{2} \\ &= \frac{\sqrt{I^2 - a^2} - \sqrt{I^2 - (a + \Delta a)^2}}{2} \end{aligned}$$

It can be seen that the axial pulling length of the pulling unit is closely related to the circumferential distance variation between the first acting portion and the second acting portion. In most cases, the circumferential distance variation of the pulling string from the unfolded configuration to the stacked configuration is less than a perimeter of the stent.

The thickness of the peripheral leakage occluder after being folded is related to the number of folds. Referring to FIG. 27c, assuming that there are three threading holes between the first acting portion X1 and the force exerting portion Y1, if the pulling string is tensioned, five layers of folds will be formed.

In a further development, the stent apparatus is a balloon expandable stent, with the stent pre-compressed onto the balloon. During release, the balloon is expanded by injected saline solution to expand the stent. With reference to FIGS. 27a and 27b, the skirt is stitched on the stent, and when the whole stent is expanded, the distance between the first action portion X1 and the second action portion X2 increases, which pulls the force application portion Y1 to move axially.

Twenty-Eighth Embodiment

Referring to FIGS. 28a to 28c, in this embodiment, the outer periphery of the stent 1 is provided with a flexible skirt 2. Before the stent 1 is released, the skirt 2 is in an unfolded configuration, which is axially unfolded and surrounds the outer periphery of the stent 1 before release. After the stent 1 is released, the skirt 2 is folded and stacked along the axial direction of the stent 1 after release into a stacked configuration and forms an annular peripheral leakage occluder.

Also provided is a pulling string 4 that is configured to drive the skirt 2 to transform into the stacked configuration. The pulling string 4 cooperates with radial deformation of the stent 1 during release. When being released in the human body, the bottom edge of the skirt 2 is released first, and the top edge of the skirt 2 is released later.

The FIG. 28a only illustrates the position of the skirt 2, in which the skirt 2 is substantially located at one axial end of the stent 1 which is adjacent to the blood inflow side (the direction of the hollow arrow in FIG. 28b indicates the normal blood flow direction when the stent is in use). The stent 1 has a meshed structure, for example, having a plurality of grids as shown in the figures. The axial length of the skirt in the unfolded configuration is half of the axial length of a grid.

The top edge of the skirt 2 is fixed on the stent, and the skirt 2 is provided with a plurality of cutting areas 5 at the

axial top side thereof, arranged in the circumferential direction. The cutting areas may reduce the radial stacking thickness of the skirt in the unfolded configuration, facilitating the load and delivery. The top edge of the skirt 2 is generally in a tooth-shaped structure extending in the circumferential direction, with a cutting area formed between two adjacent teeth, and the teeth are triangular or trapezoidal and evenly arranged in the circumferential direction.

In the case that the top edge of the skirt 2 is fixed on the stent, stitching portions may be provided only at a middle portion of the top edge of the tooth-shaped structure, with the stitching portions circumferentially spaced from each other. Developing points are provided on the stent at the stitching portions.

In this embodiment, the pulling string generally threads through the skirt in the circumferential direction. The pulling string undulates in the axial direction while extending in the circumferential direction, forming a wave-like configuration with peaks and valleys.

During the release of the stent, driven by the deformed stent, the peaks of the pulling string move away from each other in the circumferential direction and thus drive the valleys to lift upwardly. Since the pulling string movably threads through the skirt, the periodic portions thereof are configured for driving and operating in cooperation with one another, thereby generally moving the pulling string.

The portions indicated by broken line circles in the figures may serve as the threading holes 2g. The pulling string 4 only threads through the skirt, into and out of the threading holes.

In a further development, the pulling string may thread through the stent at the uppermost threading holes in the figure, which also serves as the stitching portions and thus maintains the axial position of the skirt relative to the stent.

In an unfolded configuration of the skirt, the skirt has a length indicated as a that is substantially equal to the perimeter of a corresponding portion of the stent, and the skirt has a width b which is half of the height of a grid of the stent. The length of the skirt is evenly divided into five parts, with the length of each part being c. The length of each part is equal to the length of two complete teeth. In other words, there are 10 teeth in total. Each tooth has a length d (the upper side of the trapezoid) which is equal to a distance between two adjacent teeth d. The width of the skirt is evenly divided into four parts, with the length of each part being e. The height of each tooth is e.

In the stacked configuration, each pulling unit may be folded for three times (fold is generated between two adjacent threading holes in the axial direction) to form a four-layered stack provided that a plurality of threading holes 2g are provided. By providing a plurality of threading holes, the position limiting between the pulling string and the skirt can be increased, so that the skirt can be stacked more uniformly when the skirt is pulled.

Specifically, taking a specific valve as an example, the skirt has a length a, where  $a=95\text{ mm}\pm 0.2\text{ mm}$ , and the skirt has a width b, where  $b=8.80\text{ mm}\pm 0.2\text{ mm}$ .

The length of the skirt may be divided into five parts, with the length of each part being c, where  $c=95/5=19\text{ mm}\pm 0.2\text{ mm}$ .

The tooth has a length d, and the distance between two adjacent teeth is also d, where  $d=19/4=4.75\text{ mm}\pm 0.2\text{ mm}$ .

Each tooth has a height e, where  $e=8.81/4=2.2\text{ mm}\pm 0.2\text{ mm}$ .

#### Twenty-Ninth Embodiment

Referring to FIGS. 29a to 29g, a delivery system is provided in this embodiment, which includes a handle 100,

a core shaft 102 connected to the handle 100, and a sheath 101 slidably surrounding the outer periphery of the core shaft 102. The sheath 101 is able to slide axially relative to the core shaft 102 under the control of the handle 100.

The distal end of the core shaft 102 is provided with a guide head 103 and a mounting head 104 adjacent to the guide head 103. The mounting head 104 is provided with a plurality of slots or protrusions for connecting with an implanted instrument. The implanting instrument may be, for example, the stent 105 with the skirt 107 in the above embodiments. The proximal end of the stent 105 is provided with a fixing ear 106 for engaging with the mounting head 104. In a loaded state, the stent 105 is radially compressed, located between the guide head 103 and the mounting head 104, and constrained by the sheath 101. Correspondingly, the skirt is in an unfolded configuration, and arranged around the outer periphery of the stent 105.

After the stent 105 is delivered to a desired position in the human body such as a lesion site near the aortic valve 200 by the delivery system, the sheath 101 is withdrawn relative to the core shaft 102, and the distal end of the stent 105 is first released, and is gradually exposed and begins to expand radially. Under the action of the stent 105 itself or in combination with the pulling string, the skirt 107 begins to be axially pulled and stacked. After the stent 105 is completely released, the skirt 107 transitions into a stacked configuration and forms a peripheral leakage occluder, further preventing the regurgitation at the aortic valve 200.

The features described in the above various embodiments may be combined. In order to simplify the descriptions, not all possible combinations of the features in the above embodiments have been described. However, any combinations of the features should be within the scope of the present disclosure as long as no conflict resides between these features.

The above descriptions are only specific embodiments of the present disclosure, however, the present disclosure is not limited to the embodiments. Those skilled in the art can make various modifications and variations to the embodiments without departing from the spirit and scope of the present disclosure. Obviously, these modifications and variations should fall into the scope claimed by the present disclosure. In addition, although some specific terms are used in this specification, these terms are just for convenience of illustration and do not constitute any special limitation to the present disclosure.

What is claimed is:

1. A stent apparatus, comprising:

a stent, which has

a radially compressed configuration, in which the stent has an outer periphery, an axial direction, a distal section to be released first, and a proximal section to be released later, and wherein the distal section has a meshed structure, and

a radially expanded configuration, in which the meshed structure of the distal section of the stent deforms and radially expands,

and

at least one flexible skirt made of a flexible material, which has:

an unfolded configuration, in which the skirt is axially unfolded and floats around the outer periphery of the distal section of the stent in the radially compressed configuration; and

the floating skirt is configured for constraining the outer periphery of the stent during release of the stent, which expands radially and outwardly, with a flared

configuration formed at the distal section of the stent in the radially expanded configuration for directly guiding the floating skirt to be folded and stacked in the axial direction of the stent upon further release of the stent to form a stacked configuration thereby forming an annular peripheral leakage occluder surrounding the stent in the radially expanded configuration; and

wherein the at least one skirt comprises two or more skirts which are arranged one above the other in the axial direction of the stent, and the skirts, in the stacked configuration form respective peripheral leakage occluders.

2. The stent apparatus according to claim 1, wherein the flexible material is a porcine pericardium, a bovine pericardium, or other flexible biocompatible materials.
3. The stent apparatus according to claim 1, wherein the stent is a self-expandable stent or a balloon expandable stent.
4. The stent apparatus according to claim 1, wherein the stent is configured as a valve stent or a blood vessel stent.
5. The stent apparatus according to claim 1, wherein a generatrix of the flared driving structure is a straight line, a smooth curved line, or a combination of a straight line and a curved line.

6. The stent apparatus according to claim 1, wherein one axial side edge of the stent has a sharp angled structure, and in the radially compressed configuration of the stent, the one axial side edge of the skirt does not axially extend beyond tips of the sharp angled structure.

7. The stent apparatus according to claim 1, wherein in the radially compressed configuration of the stent, at least a portion of the distal section of the stent to be released first is exposed outside the skirt, and the exposed portion is released before the skirt.

8. The stent apparatus according to claim 1, wherein a proximal end of the skirt which is to be released later is fixed on the stent, and a distal end of the skirt which is to be released first floats around the outer periphery of the stent.

9. The stent apparatus according to claim 1, wherein the stent is provided with a valve and/or a coverage membrane.

10. The stent apparatus according to claim 1, wherein a side wall of the stent is adapted to face a branch blood vessel in use, and the skirt in the stacked configuration is provided to avoid the branch vessel in an axial position.

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